

From: Claire Cassedy
Sent: Wed, 31 Jul 2019 10:03:11 -0400
To: NIH FOIA
Cc: kathryn ardizzone; James Love
Subject: Re: Letter regarding FR 45413, FR 45669, and FR 46817

Dear Mr. Bordine,

Thank you for the reply - I submitted it via the NIH FOIA Portal the July 26, 2019 request is #51843, status shows as "Assigned for Processing." Please let us know if you have any further questions.

Best Regards,
Claire Cassedy

--
Claire Cassedy
Knowledge Ecology International
1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
Tel.: 1.202.332.2670

On Tue, Jul 30, 2019 at 4:06 PM NIH FOIA <nihfoia@od.nih.gov> wrote:

Good Afternoon,

We checked out system and although there are several cases in our system that we have received from KEI, we cannot find any that were received on July 26, 2019, as is referenced in your most recent letter. Please either resend your request or let us know what the corresponding NIH FOIA Request number is for that request so that we can move forward with processing your request.

Thank you.

Roger Bordine

Program Support

Freedom of Information Office

National Institutes of Health

Building 31, Room 5B35

31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633

Fax: 301-402-4541

Roger.bordine@nih.gov



From: kathryn ardizzzone <kathryn.ardizzzone@keionline.org>
Sent: Monday, July 29, 2019 5:26 PM
To: NIH FOIA <nihfoia@od.nih.gov>
Cc: Claire Cassedy <claire.cassedy@keionline.org>; James Love <james.love@keionline.org>
Subject: Letter regarding FR 45413, FR 45669, and FR 46817

Dear Sir or Madam:

Attached, please find a letter addressed to Catherine Teti, Deputy Agency Chief FOIA Officer for the NIH, from Knowledge Ecology International (KEI), discussing three FOIA requests filed between 2016 and 2017: FR 45413, FR 45669, and FR 46817. The letter also discusses a new request, submitted July 26, 2019.

Please do not hesitate to contact me with any questions about the letter.

Sincerely,

Kathryn Ardizzzone, Esq.

Counsel

Knowledge Economy International

1621 Connecticut Avenue NW, Suite 500

Washington, DC 20009

kathryn.ardizzone@keionline.org

(202) 332-2670

From: Garcia-Malene, Gorka (NIH/OD) [E]
Sent: Fri, 6 Mar 2020 17:03:42 +0000
To: Milliard, Suzanne (NIH/NCI) [E]
Cc: NIH FOIA; Bordine, Roger (NIH/OD) [E]
Subject: RE: NHI FOIA 45669 Struver - Input

That's where I thought we'd left it.

From: Milliard, Suzanne (NIH/NCI) [E] <milliards@mail.nih.gov>
Sent: Friday, March 6, 2020 11:08 AM
To: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Cc: NIH FOIA <nihfoia@od.nih.gov>; Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: Re: NHI FOIA 45669 Struver - Input

The resolution for me was below in my email of January 23rd.

Sent from my iPhone

On Mar 5, 2020, at 5:21 PM, Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov> wrote:

Hi Suzy,

Did we ever receive any resolution on this issue? It looks like this trail went cold with Steve. Is that what you have on your end too?

Thanks,
Gorka

From: Milliard, Suzanne (NIH/NCI) [E] <milliards@mail.nih.gov>
Sent: Thursday, January 23, 2020 6:02 PM
To: Ferguson, Steve (NIH/OD) [E] <fergusos@od6100m1.od.nih.gov>; Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Cc: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>; NIH FOIA <nihfoia@od.nih.gov>; Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>; Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: Re: NHI FOIA 45669 Struver - Input

Steve-

I conferred with Richard Rodriguez that these records are internal to the government and that the official file is within OTT. While I think we (NCI) may be able to see a copy in TechTracs, under FOIA we would always go to the official record keeper for the records, which I do believe is OTT.

In the end, Gorka is the denial authority and will need to write the denial letter, since I have been told that these are not releaseable records.

I think we all need to figure this out for not only this case, but future FOIA requests.

Suzy

From: "Ferguson, Steve (NIH/OD) [E]" <fergusos@od6100m1.od.nih.gov>
Date: Thursday, January 23, 2020 at 5:56 PM
To: "Garcia-Malene, Gorka (NIH/OD) [E]" <gorka.garcia-malene@nih.gov>
Cc: "Thomas, Gina (NIH/OD) [E]" <gthomas@od.nih.gov>, NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>, "Rogers, Karen (NIH/OD) [E]" <rogersk@od.nih.gov>, "Bordine, Roger (NIH/OD) [E]" <roger.bordine@nih.gov>, "Milliard, Suzanne (NIH/NCI) [E]" <milliards@mail.nih.gov>
Subject: RE: NHI FOIA 45669 Struver - Input

Gorka –

On this request it appears that the misunderstanding may be at NCI as we certainly don't agree that the Royal Distribution Forms (RDFs) are internal OTT documents. Post-reorganization and decentralization we consider them to be in the same category as license agreements and other institute documents that are part of the license package stored in NIH TechTracs. Like the license agreements and CRADAs, these are not even stored in NIH TechTracs until they are approved and signed by the institute. A FOIA request for RDFs should be treated just like any other request for institute documents.

I realize for many years that OTT was the "go to location" regarding tech transfer-related FOIA requests – goodness knows I helped fulfill a great many of them. However NIH made a decision to directly empower the institutes to handle, manage and control their own tech transfer matters and OTT must honor that decision.

Thanks.

Steve

Steven M. Ferguson, CLP
Special Advisor
NIH Office of Technology Transfer
6011 Executive Boulevard, Suite 325
Rockville, MD 20852
Phone: (301) 435-5561
Fax: (301) 402-0220
Email: sf8h@nih.gov
Web: www.ott.nih.gov

From: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Sent: Thursday, January 23, 2020 9:03 AM
To: Ferguson, Steve (NIH/OD) [E] <fergusos@od6100m1.od.nih.gov>
Cc: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>; NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>; Rogers, Karen

(NIH/OD) [E] <rogersk@od.nih.gov>; Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>; Milliard, Suzanne (NIH/NCI) [E] <milliards@mail.nih.gov>

Subject: RE: NHI FOIA 45669 Struver - Input

Good morning, Steve,

I've conferred with NCI and think I may understand the disconnect here: The request isn't looking for CRADAs or license agreements. Instead, the requester seeks the royalty distribution form, which is an internal document to OTT.

Please let me know if we're missing anything on this end.

Best regards.

Gorka

Gorka Garcia-Malene | FOIA Officer for the National Institutes of Health | (301) 496-5633

From: Ferguson, Steve (NIH/OD) [E] <fergusos@od6100m1.od.nih.gov>

Sent: Wednesday, January 22, 2020 12:57 PM

To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>

Cc: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>; NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>; Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>

Subject: RE: NHI FOIA 45669 Struver - Input

Roger –

Sorry, but as Gina's supervisor I must insist that NCI handle this matter concerning a FOIA request regarding their various agreements with Kite.

These agreements are indeed in the central TechTracs database but since de-centralization of patent & licensing responsibilities to the institutes four years ago the existing agreements then (as well as all new agreements) are all now the responsibility of the relevant institutes. It looks like Gina mentioned this several times in the message stream below and has tried to assist with the transition various times for various cases over the past four years. However, I'm thinking that four years is sufficient as a transition period and that really we need NCI (and other ICs) to now handle their own agreement FOIA requests.

Thanks.

Regards,

Steve

Steven M. Ferguson, CLP
Special Advisor
NIH Office of Technology Transfer
6011 Executive Boulevard, Suite 325

Rockville, MD 20852
Phone: (301) 435-5561
Fax: (301) 402-0220
Email: sf8h@nih.gov
Web: www.ott.nih.gov

From: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Sent: Wednesday, January 22, 2020 12:03 PM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>; Ferguson, Steve (NIH/OD) [E] <fergusos@od6100m1.od.nih.gov>
Cc: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>; NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>
Subject: Re: NHI FOIA 45669 Struver - Input

Hi Roger - I'm forwarding this to Steve. Gina has been out of the office for extended time. Regards,
Karen

Sent from my iPhone

On Jan 22, 2020, at 11:52 AM, Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov> wrote:

Good Afternoon Gina,

Have you responded to our emails below? I can't find anything from you regarding this request.

Thank you Gina.

Roger Bordine
Program Support
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov

<[image001.png](#)>

From: Bordine, Roger (NIH/OD) [E]
Sent: Thursday, January 2, 2020 4:36 PM
To: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>
Cc: NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>
Subject: RE: NHI FOIA 45669 Struver - Input

Happy New Year Gina,

Did you already send the records you mention below? I cannot find them in any emails from you.

If not, please send them as soon as possible.

Thank you Gina.

Roger Bordine

Program Support
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633

Fax: 301-402-4541

Roger.bordine@nih.gov

<image001.png>

From: Bordine, Roger (NIH/OD) [E]
Sent: Monday, September 30, 2019 10:53 AM
To: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>
Subject: RE: NHI FOIA 45669 Struver - Input

Thank you Gina,

Yes, please send both the boxed and clean copies.

Thanks again.

- Roger

From: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>
Sent: Monday, September 30, 2019 10:50 AM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: RE: NHI FOIA 45669 Struver - Input

Roger,

NCI has access to these documents in Tech TracS.
Since I am already in the files I will pull and redact them for you.

Do you also want to see the redacted parts before I apply the redactions?

I can send you both copies. Just let me know what you need.

Gina

From: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Sent: Monday, September 30, 2019 10:45 AM
To: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>
Subject: RE: NHI FOIA 45669 Struver - Input

Thank you Gina,

Would you be able to pull the remaining Kite records specified in the request or does NC have to get those? Either way, since we can't redact the whole document, we'll have to pull these records and then redact the portions you've shown.

Thanks Gina.

- Roger

From: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>
Sent: Monday, September 30, 2019 10:30 AM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: RE: NHI FOIA 45669 Struver - Input

Roger,

The Royalty Distribution Forms KEI is requesting are protected under Exemption 4. They are business confidential as they provide the breakdown and percentages of how much each inventors get with Royalties. This information is protected.

KEI knows they cannot get Royalty Rates and we have never provided these forms publicly. They also know that the only thing we can freely give them from a CRADA is the summary sheets (the summary only gives name of and a general reason for the CRADA). Any and ALL financial information and terms from a license would be redacted.

Most of these old request that KEI are sending back through were denied based on Exemption 4. Any request looking for Royalty Rates, a company's business information and negotiated terms between NIH and the Company will not be released.

The Royalty distribution forms are attached to the records in our Tech TracS database. NCI has access to these records, however...they should not be releasing this information (without redactions) based on Exemption 4.

If we gave them a copy of the RDF it would be heavily redacted. They would not be privy to the breakdown or what each inventor is receiving Royalties. I have provided a copy of 1 of these RDF's redacted so you can see what that would look like.

Kite has multiple applications with NCI. All Royalty Forms would be redacted the same way.

Let me know how you would like to proceed.

Gina

From: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>

Sent: Friday, September 27, 2019 4:03 PM

To: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>

Subject: NHI FOIA 45669 Struver - Input

Hi Gina,

We have really old request and need to know if OTT would have any of the records listed in the attached copy of the request.

NCI said OTT would have these records.

Thanks Gina.

Roger Bordine

Program Support

Freedom of Information Office

National Institutes of Health

Building 31, Room 5B35

31 Center Drive

Bethesda, MD 20892

Phone: 301-496-5633

Fax: 301-402-4541

Roger.bordine@nih.gov

<[image001.png](#)>

From: Bordine, Roger (NIH/OD) [E]
Sent: Thu, 2 Jan 2020 21:30:28 +0000
To: Broyles, Stephanie (NIH/OD) [E]
Cc: OFM Helpdesk; NIH FOIA
Subject: RE: NHI FOIA Request for Input - Love 46817

Hi Stephanie,

Is there an update on this request? We have attempted to contact you for a long time on this FOIA request. Is there someone else at OFM that we should be contacting in your absence?

Thank you.

Roger Bordine
Program Support
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov



From: NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>
Sent: Friday, September 27, 2019 3:50 PM
To: Broyles, Stephanie (NIH/OD) [E] <broyles@od.nih.gov>
Cc: NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>
Subject: RE: NHI FOIA Request for Input - Love 46817

Hi Stephanie,

Could you please send us an update on this request? It has been over a year and we cannot find any response from you.

Thank you.

Roger Bordine
Program Support
Freedom of Information Office

National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov



From: Broyles, Stephanie (NIH/OD) [E] <broyless@od.nih.gov>
Sent: Thursday, May 31, 2018 1:16 PM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Cc: NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>
Subject: RE: NHI FOIA Request for Input - Love 46817

Roger - let me look into it. Sometimes I don't receive a copy of the final product.

Stephanie

Stephanie L. Broyles
Office of Financial Management
2115 East Jefferson Street
Room 3C308
Rockville, MD 20852 (Deliveries Only)
Bethesda, MD 20892 (U.S. Mail only)
301-402-6260 (phone)
301-451-5545 (fax)

From: Bordine, Roger (NIH/OD) [E]
Sent: Thursday, May 31, 2018 1:12 PM
To: Broyles, Stephanie (NIH/OD) [E] <BroylesS@od.nih.gov>
Cc: NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>
Subject: RE: NHI FOIA Request for Input - Love 46817

Hi Stephanie,

Any word on the status of this search?

Thank you Stephanie.

Roger Bordine

Program Assistant
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov



From: Bordine, Roger (NIH/OD) [E]
Sent: Monday, October 2, 2017 9:27 AM
To: Broyles, Stephanie (NIH/OD) [E] <BroylesS@od.nih.gov>
Subject: RE: NHI FOIA Request for Input - Love 46817

Good Morning Stephanie,

No, we have yet to receive a response from OFM.

Thank you.

Roger Bordine

Program Assistant
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov



From: Broyles, Stephanie (NIH/OD) [E]
Sent: Saturday, September 30, 2017 7:02 AM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: RE: NHI FOIA Request for Input - Love 46817

Good morning Roger -

Did you get any response from OFM?

Stephanie L. Broyles
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2115 East Jefferson Street
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Bethesda, MD 20892 (U.S. Mail only)
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301-451-5545 (fax)

From: Bordine, Roger (NIH/OD) [E]
Sent: Wednesday, August 30, 2017 5:09 PM
To: Broyles, Stephanie (NIH/OD) [E] <broyless@od.nih.gov>
Cc: NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>
Subject: NHI FOIA Request for Input - Love 46817

Good Afternoon Stephanie,

Please see the attached request for input regarding a copy of who received royalties from the NIH in 2016.

Thank you Stephanie, and please let me know if you have any questions.

Roger Bordine
Program Assistant
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov



National Institutes of Health
Turning Discovery Into Health

From: NIH FOIA
Sent: Thu, 17 Oct 2019 17:00:37 +0000
To: OFM Helpdesk
Cc: NIH FOIA
Subject: RE: NHI FOIA Request for Input - Love 46817

Good Afternoon,

We have not received word back from Stephanie Broyles regarding several FOIA requests sent to OFM for input. Is there an additional contact/staff member our office can reach out to for statuses of FOIA records searches at OFM?

Thank you.

Roger Bordine
Program Support
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov



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Sent: Friday, September 27, 2019 3:50 PM
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Roger Bordine
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Freedom of Information Office

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Stephanie

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Subject: RE: NHI FOIA Request for Input - Love 46817

Hi Stephanie,

Any word on the status of this search?

Thank you Stephanie.

Roger Bordine

Program Assistant
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Phone: 301-496-5633
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From: Bordine, Roger (NIH/OD) [E]
Sent: Monday, October 2, 2017 9:27 AM
To: Broyles, Stephanie (NIH/OD) [E] <BroylesS@od.nih.gov>
Subject: RE: NHI FOIA Request for Input - Love 46817

Good Morning Stephanie,

No, we have yet to receive a response from OFM.

Thank you.

Roger Bordine

Program Assistant
Freedom of Information Office
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Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

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From: Broyles, Stephanie (NIH/OD) [E]
Sent: Saturday, September 30, 2017 7:02 AM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: RE: NHI FOIA Request for Input - Love 46817

Good morning Roger -

Did you get any response from OFM?

Stephanie L. Broyles
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To: Broyles, Stephanie (NIH/OD) [E] <broyless@od.nih.gov>
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Subject: NHI FOIA Request for Input - Love 46817

Good Afternoon Stephanie,

Please see the attached request for input regarding a copy of who received royalties from the NIH in 2016.

Thank you Stephanie, and please let me know if you have any questions.

Roger Bordine
Program Assistant
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov



From: Bordine, Roger (NIH/OD) [E]
Sent: Fri, 27 Sep 2019 20:22:28 +0000
To: Garcia-Malene, Gorka (NIH/OD) [E]
Subject: 45413 Love - Final Denial Draft
Attachments: 45413 Love - Final Response.docx

Hi Gorka,

Attached is the draft of the final denial letter to Love/KEI for 45413. Please review and sign.

Thanks.

Roger Bordine
Program Support
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via email: james.love@keionline.org

September 27, 2019

James Love
Director
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009

Re: FOI Case No. 45413

Dear Mr. Love:

This is the final response to your August 8, 2016, Freedom of Information Act (FOIA) request addressed to the Freedom of Information (FOIA) Office, National Institutes of Health (NIH), which was received in our office on August 11, 2016. You requested a copy the following:

1. All records related to individual royalty payments for licensed technologies received by current and former federal employees for whom the NIH administers royalty payments, including employees of the NIH, Centers for Disease Control (CDC), and the Food and Drug Administration (FDA) between August 8, 2011 and August 8, 2016; and
2. Any and all communications and correspondence, in the form of emails, briefings, notes presentations or other formats, to or from employees of the NIH, CDC, and FDA that mention the payment of the royalties in Item 1 to current or former individual employees of the NIH, CDC, and FDA between August 8, 2011 and August 8, 2016.

Please be advised that the volume of records to be searched in response to Item 2 of your request exceeds 1,000 email accounts, and would deem that portion of your request to be overly broad, as stipulated by the FOIA. Therefore, Item 2 of your request cannot be processed as it is written, as it places an undue burden on federal government resources.

The NIH Office of Technology Transfer (OTT) was consulted regarding records responsive to your request. I have determined to withhold those records pursuant to Exemptions 3 and 4 of the FOIA, 5 U.S.C. § 552 (b)(3) and (b)(4), and section 5.64 and 5.65 of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 3 protects from release records that are specifically exempt from disclosure by another federal statute. In this instance, the statute in question is the Federal Transfer and Technology Act, 15 U.S.C. Section 3710 a(c)(7)(A). Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged and confidential. In this case, the information withheld consists of non-public research.

You have the right to appeal this determination to deny you access to information in the Agency's possession. Should you wish to do so, your appeal must be sent within ninety (90) days of the date of this letter, following the procedures outlined in Subpart F of the HHS FOIA Regulations (<https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations>) to:

Assistant Secretary for Public Affairs
Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs, Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

Clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

If you are not satisfied with the processing and handling of this request, you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison

Stephanie Clipper
Public Affairs Specialist
Office of Communications and Public Liaison
Building 1 Room 331
1 Center Drive
Bethesda, MD 20892
301-496-1828 (phone)
nihfoia@mail.nih.gov (email)

OGIS

National Archives and Records Admin.
8601 Adelphi Rd – OGIS
College Park, MD 20740-6001
202-741-5770 (phone)
1-877-684-6448 (toll-free)
202-741-5769 (fax)
ogis@nara.gov (email)

In certain circumstances provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there is no charge associated with our response.

If you have any questions about this response, please call 301-496-5633.

Sincerely,

Gorka Garcia-Malene
Freedom of Information Officer, NIH

From: Garcia-Malene, Gorka (NIH/OD) [E]
Sent: Thu, 17 Oct 2019 16:35:19 +0000
To: Bordine, Roger (NIH/OD) [E]
Subject: 46817

Hi Roger,

Did we ever receive records for this one?

From: Lampe, Karen (NIH/OD) [E]
Sent: Thu, 21 May 2020 12:13:43 +0000
To: Garcia-Malene, Gorka (NIH/OD) [E]
Subject: FW: Case 45669 Struver
Attachments: 45669 Final Response_Redacted.pdf, 45669 Struver - Final Response.docx, Copy of Request 45669 with NIH FOIA notes written.pdf

In case you didn't see this earlier this week.

From: Lampe, Karen (NIH/OD) [E]
Sent: Monday, May 18, 2020 11:39 AM
To: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Subject: Case 45669 Struver

Hi Gorka,
Attached is a draft final letter for your review and signature. I've also attached a copy of the redacted records and the request. Let me know if you have any questions.

Karen E. R. Lampe, Ph.D.
Government Information Specialist
NIH Freedom of Information Office (HNA83)
karen.lampe@nih.gov

ROYALTY DISTRIBUTION FORM

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LICENSE INFORMATION

Generation Date: 12/02/2015

Due Date: 01/01/2016

☒ New License

☐ Amendment

☐ Amended Distribution

License Application	License Number	Fiscal Year	License Type	License Category
A-276-2014	L-002-2016/0		New	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☐ No ☐ Yes

Technologies

Reference No. Lead IC Title

A (b) (4)

B

Inventors

<u>Inventor's Name</u>	<u>Orig IC</u>	<u>Technologies</u>	<u>Inv Total</u>	<u>Default Inventor %</u>	<u>Alternate Inventor %</u>
(b) (4), (b) (6)	NCI	A, B	2	25	
	NCI	A, B	2	25	
	NCI	A	1	12.5	
	NCI	A	1	12.5	
	NCI	A	1	12.5	
	NCI	B	1	12.5	
Totals:			8	100	

ICs

<u>IC Name</u>	<u>Technologies</u>	<u>IC Total</u>	<u>Default IC %</u>	<u>Alternate IC %</u>
NCI	A, B	8	100	
Totals:		8	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
1.			
2.			
3.			
4.			

ROYALTY DISTRIBUTION FORM

OTT AUTHORIZING OFFICIAL

Whitney Hastings

SIGNATURE

DATE

Andrew Burke

Digitally signed by Andrew R. Burke -S-
(Affiliate)
DN: c=US, o=U.S. Government,
ou=HHS, ou=NIH, ou=People,
0.9.2342.19200300.100.1.1=20008140
29, cn=Andrew R. Burke -S (Affiliate)
Date: 2015.12.02 13:50:48 -05'00'

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LICENSE INFORMATION

Generation Date: 04/05/2016

Due Date: 05/05/2016

☐ New License

☒ Amendment

☐ Amended Distribution

License Application	License Number	Fiscal Year	License Type	License Category
A-224-2016	L-002-2016/1	2016	Amendment	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A (b) (4)

B

Inventors

<u>Inventor's Name</u>	<u>Orig IC</u>	<u>Technologies</u>	<u>Inv Total</u>	<u>Default Inventor %</u>	<u>Alternate Inventor %</u>
(b) (4), (b) (6)	NCI	A, B	2	25	
	NCI	A, B	2	25	
	NCI	A	1	12.5	
	NCI	A	1	12.5	
	NCI	A	1	12.5	
	NCI	B	1	12.5	
Totals:			8	100	

ICs

<u>IC Name</u>	<u>Technologies</u>	<u>IC Total</u>	<u>Default IC %</u>	<u>Alternate IC %</u>
NCI	A, B	8	100	
Totals:		8	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
1.			
2.			
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4.			

ROYALTY DISTRIBUTION FORM

OTT AUTHORIZING OFFICIAL

Andrew R. Burke

SIGNATURE

debbie.collins@nih.gov

DATE

Digitally signed by
debbie.collins@nih.gov
DN: cn=debbie.collins@nih.gov
Date: 2016.04.05 09:12:07 -04'00'

OV

ROYALTY DISTRIBUTION FORM

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LICENSE INFORMATION

Generation Date: 04/17/2013

Due Date: 05/17/2013

☒ New License

☐ Amendment

☐ Amended Distribution

License Application	License Number	Fiscal Year	License Type	License Category
A-294-2011	L-068-2013/0	2013	New	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A

(b) (4)

B

Inventors

<u>Inventor's Name</u>	<u>Orig IC</u>	<u>Technologies</u>	<u>Inv Total</u>	<u>Default Inventor %</u>	<u>Alternate Inventor %</u>
(b) (4), (b) (6)	NCI	A, B	2	40	
	NCI	A	1	20	
	NCI	A, B	2	40	
Totals:			5	100	

ICs

<u>IC Name</u>	<u>Technologies</u>	<u>IC Total</u>	<u>Default IC %</u>	<u>Alternate IC %</u>
NCI	A, B	5	100	
Totals:		5	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
1.			
2.			
3.			
4.			

OTT AUTHORIZING OFFICIAL

SIGNATURE	DATE
Samuel E. Bish	04-17-2013

Digitally signed by Samuel E. Bish
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH,
ou=People, cn=Samuel E. Bish,
0.9.2342.19200300.100.1.1=0013640079
Date: 2013.04.17 11:00:38 -04'00'

ROYALTY DISTRIBUTION FORM

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LICENSE INFORMATION

Generation Date: 10/23/2015

Due Date: 11/22/2015

☐ New License

☒ Amendment

☐ Amended Distribution

License Application	License Number	Fiscal Year	License Type	License Category
A-411-2015	L-068-2013/1		Amendment	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☐ No ☐ Yes

Technologies

Reference No. Lead IC Title

A	(b) (4)	
B		

Inventors

<u>Inventor's Name</u>	<u>Orig IC</u>	<u>Technologies</u>	<u>Inv Total</u>	<u>Default Inventor %</u>	<u>Alternate Inventor %</u>
(b) (4), (b) (6)	NCI	A, B	2	40	
	NCI	A	1	20	
	NCI	A, B	2	40	
Totals:			5	100	

ICs

<u>IC Name</u>	<u>Technologies</u>	<u>IC Total</u>	<u>Default IC %</u>	<u>Alternate IC %</u>
NCI	A, B	5	100	
Totals:		5	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
1.			
2.			
3.			
4.			

OTT AUTHORIZING OFFICIAL

Whitney Hastings	SIGNATURE Andrew R. Burke	DATE
	-S (Affiliate)	

Digitally signed by Andrew R. Burke, S (Affiliate)
DN: c=US, o=U.S. Government, ou=HHS
ou=NIH, ou=People
0.9.2342.1.9200300.100.1.1.2000814029
cn=Andrew R. Burke, S (Affiliate)
Date: 2015.10.23 13:37:20 -0400

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LICENSE INFORMATION

Generation Date: 04/05/2016

Due Date: 05/05/2016

☐ New License

☒ Amendment

☐ Amended Distribution

License Application	License Number	Fiscal Year	License Type	License Category
A-225-2016	L-068-2013/2	2016	Amendment	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A	(b) (4)	
B		

Inventors

<u>Inventor's Name</u>	<u>Orig IC</u>	<u>Technologies</u>	<u>Inv Total</u>	<u>Default Inventor %</u>	<u>Alternate Inventor %</u>
(b) (4), (b) (6)	NCI	A, B	2	40	
	NCI	A	1	20	
	NCI	A, B	2	40	
Totals:			5	100	

ICs

<u>IC Name</u>	<u>Technologies</u>	<u>IC Total</u>	<u>Default IC %</u>	<u>Alternate IC %</u>
NCI	A, B	5	100	
Totals:		5	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
1.			
2.			
3.			
4.			

OTT AUTHORIZING OFFICIAL

Andrew R. Burke

SIGNATURE

DATE

debbie.collins@nih.gov

Digitally signed by debbie.collins@nih.gov
DN: cn=debbie.collins@nih.gov
Date: 2016.04.05 09:16:46 -04'00'

V

ROYALTY DISTRIBUTION FORM

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LICENSE INFORMATION

Generation Date: 01/11/2015

Due Date: 02/10/2015

☒ New License

☐ Amendment

☐ Amended Distribution

License Application	License Number	Fiscal Year	License Type	License Category
A-563-2014	L-077-2015/0	2015	New	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A	(b) (4)		
B			

Inventors

Inventor's Name	Orig IC	Technologies	Inv Total	Default Inventor %	Alternate Inventor %
(b) (4), (b) (6)	NCI	A, B	2	50	
	NCI	A, B	2	50	
Totals:			4	100	

ICs

IC Name	Technologies	IC Total	Default IC %	Alternate IC %
NCI	A, B	4	100	
Totals:		4	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
1.	Karen Maurey, Director		9/30/15
2.	NIH TTC	Keith A. Bupp - S	
3.			
4.			

Digitally signed by Keith A. Bupp - S
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, cn=Keith A. Bupp - S, 0.9.2342.19200300.1.001.1=0012754217
Date: 2015.09.30 11:46:11 -0400

for KM

OTT AUTHORIZING OFFICIAL

NAME	SIGNATURE	DATE
Whitney Hastings	Whitney A. Hastings - S	

Digitally signed by Whitney A. Hastings - S
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0011496767, cn=Whitney A. Hastings - S
Date: 2015.01.11 15:53:06 -0500

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LICENSE INFORMATION

Generation Date: 07/13/2015

Due Date: 08/12/2015

☐ New License

☒ Amendment

☐ Amended Distribution

License Application	License Number	Fiscal Year	License Type	License Category
A-274-2015			Amendment	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A

(b) (4)

B

Inventors

<u>Inventor's Name</u>	<u>Orig IC</u>	<u>Technologies</u>	<u>Inv Total</u>	<u>Default Inventor %</u>	<u>Alternate Inventor %</u>
(b) (4), (b) (6)	NCI	A, B	2	50	
	NCI	A, B	2	50	
Totals:			4	100	

ICs

<u>IC Name</u>	<u>Technologies</u>	<u>IC Total</u>	<u>Default IC %</u>	<u>Alternate IC %</u>
NCI	A, B	4	100	
Totals:		4	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☒ Default Formula

☐ Alternative Distribution

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
1.	Karen Maurey, Director		9/30/15
2.	NCI TTC		
3.			
4.		Keith A. Bupp -S for KM	

OTT AUTHORIZING OFFICIAL

NAME	SIGNATURE	DATE
Whitney Hastings	Whitney A. Hastings -S	

ROYALTY DISTRIBUTION FORM

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LICENSE INFORMATION

Generation Date: 04/05/2016

Due Date: 05/05/2016

☐ New License

☒ Amendment

☐ Amended Distribution

License Application	License Number	Fiscal Year	License Type	License Category
A-229-2016	L-077-2015/2	2016	Amendment	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A	(b) (4)	
B		

Inventors

<u>Inventor's Name</u>	<u>Orig IC</u>	<u>Technologies</u>	<u>Inv Total</u>	<u>Default Inventor %</u>	<u>Alternate Inventor %</u>
(b) (4), (b) (6)	NCI	A, B	2	50	
	NCI	A, B	2	50	
Totals:			4	100	

ICs

<u>IC Name</u>	<u>Technologies</u>	<u>IC Total</u>	<u>Default IC %</u>	<u>Alternate IC %</u>
NCI	A, B	4	100	
Totals:		4	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
1.			
2.			
3.			
4.			

OTT AUTHORIZING OFFICIAL

Andrew R. Burke	SIGNATURE	DATE
	debbie.collins@nih.gov	Digitally signed by debbie.collins@nih.gov DN: cn=debbie.collins@nih.gov Date: 2016.04.05 09:21:18 -04'00'
	OV	

ROYALTY DISTRIBUTION FORM

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LICENSE INFORMATION

Generation Date: 02/28/2020

Generated by: Bryantk

Due Date: 03/29/2020

☒ New License

☐ Amendment

☐ Amended Distribution

License Application	License Number	Lead Institute	Fiscal Year	License Type	License Category
A-315-2017	L-099-2020-0	NCI/CCR	2020	New	Patent-Commercial

Licensee: Kite Pharma

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No.	Lead IC	Title
A		(b) (4)
B		
C		
D		
E		
F		

Inventors

Inventor's Name	Orig IC	Technologies	Inv Total	Default Inventor %	Alternate Inventor %
(b) (4), (b) (6)	NCI	A, B, C, D, E, F	6	50	
	NCI	A, B, C, D, E, F	6	50	
Totals:			12	100	

ICs

IC Name	Technologies	IC Total	Default IC %	Alternate IC %
NCI	A, B, C, D, E, F	12	100	
Totals:		12	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

ROYALTY DISTRIBUTION FORM

Reviewed by Negotiator

NAME

Andrew Ryan Burke

SIGNATURE



DATE

February 28, 2020

IC AUTHORIZING OFFICIAL(S)

IC

NAME

SIGNATURE

DATE

NCI

Remarks

ROYALTY DISTRIBUTION FORM

IC must complete and submit this form to NIH OTT Royalties Admin Unit. The completed form should be forwarded through the OTT SharePoint site.

LICENSE INFORMATION

Generation Date: 04/30/2019 Generated by: Collinsde Due Date: 05/30/2019

☒ New License

☐ Amendment

☐ Amended Distribution

License Application	License Number	Lead Institute	Fiscal Year	License Type	License Category
A-325-2016	L-149-2019-0	NCI/CCR	2019	New	Patent-Commercial

Licensee: Kite Pharma

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A (b) (4)

Inventors

<u>Inventor's Name</u>	<u>Orig IC</u>	<u>Technologies</u>	<u>Inv Total</u>	<u>Default Inventor %</u>	<u>Alternate Inventor %</u>
(b) (4), (b) (6)	NCI	A	1	33.33	
	NCI	A	1	33.33	
	NCI	A	1	33.34	
Totals:			3	100	

ICs

<u>IC Name</u>	<u>Technologies</u>	<u>IC Total</u>	<u>Default IC %</u>	<u>Alternate IC %</u>
NCI	A	3	100	
Totals:		3	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

Reviewed by Negotiator

NAME	SIGNATURE	DATE
Andrew R. Burke	 Deborah Collins-S	Digitally signed by Deborah Collins-S

IC AUTHORIZING OFFICIAL(S)

Date: 2019.04.30 17:03:51 -04'00'

IC	NAME	SIGNATURE	DATE
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NCI

Remarks

ROYALTY DISTRIBUTION FORM

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LICENSE INFORMATION

Generation Date: 07/12/2016 Generated by: henrysi Due Date: 08/11/2016

☒ New License

☐ Amendment

☐ Amended Distribution

License Application	License Number	Lead Institute	Fiscal Year	License Type	License Category
A-238-2015	L-218-2016/0	NCI/CCR	2016	New	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A (b) (4)

Inventors

<u>Inventor's Name</u>	<u>Orig IC</u>	<u>Technologies</u>	<u>Inv Total</u>	<u>Default Inventor %</u>	<u>Alternate Inventor %</u>
(b) (4), (b) (6)	NCI	A	1	100	
Totals:			1	100	

ICs

<u>IC Name</u>	<u>Technologies</u>	<u>IC Total</u>	<u>Default IC %</u>	<u>Alternate IC %</u>
NCI	A	1	100	
Totals:		1	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

Reviewed by Negotiator

NAME	SIGNATURE	DATE
David A. Lambertson	David A. Lambertson - S	Digitally signed by David A. Lambertson - S DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0012360025, cn=David A. Lambertson - S Date: 2016.07.20 11:37:14 -0400

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
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NCI

Remarks

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IC must complete and submit this form to NIH OTT Royalties Admin Unit. The completed form should be forwarded through the OTT SharePoint site.

LICENSE INFORMATION

Generation Date: 11/29/2016 Generated by: henrysi Due Date: 12/29/2016

☐ New License

☒ Amendment

☐ Amended Distribution

License Application	License Number	Lead Institute	Fiscal Year	License Type	License Category
A-022-2017		NCI/CCR	2017	Amendment	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A (b) (4)

Inventors

Inventor's Name	Orig IC	Technologies	Inv Total	Default Inventor %	Alternate Inventor %
(b) (4), (b) (6)	NCI	A	1	100	
Totals:			1	100	

ICs

IC Name	Technologies	IC Total	Default IC %	Alternate IC %
NCI	A	1	100	
Totals:		1	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

Reviewed by Negotiator

NAME	SIGNATURE	DATE
David A. Lambertson	David A. Lambertson -S	

Digitally signed by David A. Lambertson
DN: c=US, o=U.S. Government, ou=HHS,
ou=NIH, ou=People, o=923421920030010011-0012360025, cn=David A.
Lambertson, S
Date: 2016.12.05 06:35:52 -05:00

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
NCI			

Remarks

ROYALTY DISTRIBUTION FORM

IC must complete and submit this form to NIH OTT Royalties Admin Unit. The completed form should be forwarded through the OTT SharePoint site.

LICENSE INFORMATION

Generation Date: 08/31/2016 Generated by: henrysi Due Date: 09/30/2016

☒ New License

☐ Amendment

☐ Amended Distribution

License Application	License Number	Lead Institute	Fiscal Year	License Type	License Category
A-078-2016	L-259-2016/0	NCI/CCR	2016	New	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A	(b) (4)	
B		

Inventors

<u>Inventor's Name</u>	<u>Orig IC</u>	<u>Technologies</u>	<u>Inv Total</u>	<u>Default Inventor %</u>	<u>Alternate Inventor %</u>
(b) (4), (b) (6)	NCI	A, B	2	40	
	NCI	A, B	2	40	
	NCI	B	1	20	
Totals:			5	100	

ICs

<u>IC Name</u>	<u>Technologies</u>	<u>IC Total</u>	<u>Default IC %</u>	<u>Alternate IC %</u>
NCI	A, B	5	100	
Totals:		5	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

Reviewed by Negotiator

NAME	SIGNATURE	DATE
Andrew R. Burke		

Digitally signed by Andrew R. Burke - S
(Affiliate)
DN: cn=US, o=U.S. Government,
ou=HRIS, ou=NIH, ou=People,
0.9.2342.19200300.100.1.1=20008140
29, cn=Andrew R. Burke - S (Affiliate)
Date: 2016.09.01 14:11:43 -0400

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
NCI			

Remarks

ROYALTY DISTRIBUTION FORM

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LICENSE INFORMATION

Generation Date: 09/16/2016 Generated by: henrysi Due Date: 10/16/2016

☐ New License

☒ Amendment

☐ Amended Distribution

License Application	License Number	Lead Institute	Fiscal Year	License Type	License Category
A-490-2016	L-259-2016/1	NCI/CCR	2016	Amendment	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A	(b) (4)	
B		
C		
D		
E		

Inventors

<u>Inventor's Name</u>	<u>Orig IC</u>	<u>Technologies</u>	<u>Inv Total</u>	<u>Default Inventor %</u>	<u>Alternate Inventor %</u>
(b) (4), (b) (6)	NCI	A, B, C	3	18.75	
	NCI	A, B, C	3	18.75	
	NCI	C	1	6.25	
	NCI	D, E	2	12.5	
	NCI	D, E	2	12.5	
	NCI	D, E	2	12.5	
	NCI	E	1	6.25	
	NCI	E	1	6.25	
	NCI	E	1	6.25	
Totals:			16	100	

<u>ICs</u>	<u>Technologies</u>	<u>IC Total</u>	<u>Default IC %</u>	<u>Alternate IC %</u>
NCI	A, B, C, D, E	16	100	
Totals:		16	100	

ROYALTY DISTRIBUTION FORM

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

Reviewed by Negotiator

NAME

SIGNATURE

Digitally signed by Andrew R. Burke -5
(Affiliate)

DATE

Andrew R. Burke

Andrew Burke

DN: cn=US, ou=US Government, ou=HHS,
ou=NIH, ou=People,
0.9.2342.19200300.100.1.1=2000814029
, cn=Andrew R. Burke -5 (Affiliate)
Date: 2016.09.16 16:19:19 -0400

IC AUTHORIZING OFFICIAL(S)

IC

NAME

SIGNATURE

DATE

NCI

Remarks

ROYALTY DISTRIBUTION FORM

IC must complete and submit this form to NIH OTT Royalties Admin Unit. The completed form should be forwarded through the OTT SharePoint site.

LICENSE INFORMATION

Generation Date: 06/12/2018 Generated by: burkear Due Date: 07/12/2018

☐ New License

☒ Amendment

☐ Amended Distribution

License Application	License Number	Lead Institute	Fiscal Year	License Type	License Category
A-154-2018	L-259-2016-2	NCI/CCR	2018	Amendment	Patent-Commercial

Licensee: Kite Pharma

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A

B

C

D

E

F

G

(b) (4)

Inventors

Inventor's Name

Orig IC Technologies

Inv
Total

Default
Inventor %

Alternate
Inventor %

ROYALTY DISTRIBUTION FORM

(b) (4), (b) (6)

NCI	A, B, C	3	12
NCI	A, B, C	3	12
NCI	B, C	2	8
NCI	D, E	2	8
NCI	D, E, G	3	12
NCI	D, E, F, G	4	16
NCI	E, F	2	8
NCI	E	1	4
NCI	E	1	4
NCI	F, G	2	8
NCI	F, G	2	8

Totals: 25 100

ICs

IC Name

Technologies

IC

Total

Default IC %

Alternate IC %

NCI

A, B, C, D, E, F, G

25

100

Totals: 25 100

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

Reviewed by Negotiator

NAME

SIGNATURE

Digitally signed by Andrew R. Burke -S

DATE

Andrew R. Burke

Andrew R. Burke

DN: cn=IC, ou=US, email=

CN=IC, ou=US, email=

0.9.2342.19200300.100.1.1=200801402

S. cn=Andrew R. Burke -S

IC AUTHORIZING OFFICIAL(S)

IC

NAME

SIGNATURE

DATE

NCI

Richard U.

Rodriguez -S

Digitally signed by

Richard U. Rodriguez -S

Date: 2018.07.02

13:44:32 -04'00'

Remarks

ROYALTY DISTRIBUTION FORM

IC must complete and submit this form to NIH OTT Royalties Admin Unit. The completed form should be forwarded through the OTT SharePoint site.

LICENSE INFORMATION

Generation Date: 04/02/2019

Generated by: Collinsde

Due Date: 05/02/2019

☐ New License

☒ Amendment

☐ Amended Distribution

License Application	License Number	Lead Institute	Fiscal Year	License Type	License Category
A-203-2019	L-259-2016-3	NCI/CCR	2019	Amendment	Patent-Commercial

Licensee: Kite Pharma

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

	<u>Reference No.</u>	<u>Lead IC</u>	<u>Title</u>
A	(b) (4)		
B			
C			
D			
E			
F			
G			
H			

Inventors

Inventor's Name

Orig IC

Technologies

Inv
Total

Default
Inventor %

Alternate
Inventor %

ROYALTY DISTRIBUTION FORM

(b) (4), (b) (6)

NCI	A, B, C	3	11.11
NCI	A, B, C, H	4	14.82
NCI	B, C,	2	7.41
NCI	D, E	2	7.41
NCI	D, E, G	3	11.11
NCI	D, E, F, G	4	14.81
NCI	E, F	2	7.41
NCI	E	1	3.7
NCI	E	1	3.7
NCI	F, G	2	7.41
NCI	F, G	2	7.41
NCI	H	1	3.7

Totals: 27 100

ICs

IC Name
NCI

Technologies
A, B, C, D, E, F, G, H

IC Total	Default IC %	Alternate IC %
27	100	

Totals: 27 100

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

Reviewed by Negotiator

NAME

Andrew R. Burke

SIGNATURE

Andrew R. Burke

DATE

April 2, 2019

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
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NCI

Remarks

RDF revised per email from Andy Burle - removed one inventor (b) (4), (b) (6) and dropped technology "H" from (b) (4), (b) (6)

ROYALTY DISTRIBUTION FORM

IC must complete and submit this form to NIH OTT Royalties Admin Unit. The completed form should be forwarded through the OTT SharePoint site.

LICENSE INFORMATION

Generation Date: 06/25/2019

Generated by: Collinsde

Due Date: 07/25/2019

☐ New License

☒ Amendment

☐ Amended Distribution

License Application	License Number	Lead Institute	Fiscal Year	License Type	License Category
A-364-2019	L-259-2016-4	NCI/CCR	2019	Amendment	Patent-Commercial

Licensee: Kite Pharma

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

	Reference No.	Lead IC	Title	
A	(b) (4)			
B				
C				
D				
E				
F				
G				
H				
I				

Inventors

<u>Inventor's Name</u>	<u>Orig IC</u>	<u>Technologies</u>	<u>Inv Total</u>	<u>Default Inventor %</u>	<u>Alternate Inventor %</u>
------------------------	----------------	---------------------	----------------------	-------------------------------	---------------------------------

ROYALTY DISTRIBUTION FORM

(b) (4), (b) (6)

NCI	I	1	3.22
NCI	A, B, C	3	9.67
NCI	A, B, C, H	4	12.9
NCI	B, C	2	6.45
NCI	D, E	2	6.45
NCI	D, E, G	3	9.67
NCI	D, E, F, G, I	5	16.18
NCI	E, F	2	6.45
NCI	E, I	2	6.45
NCI	E	1	3.22
NCI	F, G, I	3	9.67
NCI	F, G	2	6.45
NCI	H	1	3.22

Totals: 31 100

ICs		IC		
IC Name	Technologies	Total	Default IC %	Alternate IC %
NCI	A, B, C, D, E, F, G, H, I	31	100	
		Totals:	<u>31</u>	<u>100</u>

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

Reviewed by Negotiator

NAME	SIGNATURE	DATE
Andrew Ryan Burke	Deborah Collins-S	Digitally signed by Deborah

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
NCI			

Remarks

ROYALTY DISTRIBUTION FORM

IC must complete and submit this form to NIH OTT Royalties Admin Unit. The completed form should be forwarded through the OTT SharePoint site.

LICENSE INFORMATION

Generation Date: 11/30/2018 Generated by: Collinsde Due Date: 12/30/2018

☒ New License

☐ Amendment

☐ Amended Distribution

License Application	License Number	Lead Institute	Fiscal Year	License Type	License Category
A-279-2015	L-268-2016-0	NCI/CCR	2016	New	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No.	Lead IC	Title
A	(b) (4)	(b) (4)
B	(b) (4)	(b) (4)

Inventors

Inventor's Name	Orig IC	Technologies	Inv Total	Default Inventor %	Alternate Inventor %
(b) (4), (b) (6)	NCI	A, B	2	50	
	NCI	A, B	2	50	
Totals:			4	100	

ICs

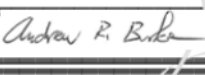
IC Name	Technologies	IC Total	Default IC %	Alternate IC %
NCI	A, B	4	100	
Totals:		4	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

Reviewed by Negotiator

NAME	SIGNATURE	DATE
Andrew R. Burke		

Digitally signed by Andrew R. Burke - 5
DN: c=US, o=US Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=2000814
0.9.2342.19200300.100.1.1=2000814
Date: 2018.12.06 12:47:07 -0500

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
NCI			

Added /1 per email from (b) (4), (b) (6) -The technologies identified on page two are (b) (4) and (b) (4); the technologies in (b) (4) are not yet expired, e.g. the US application is still alive and expires 2/14/2035:

Remarks

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LICENSE INFORMATION

Generation Date: 06/18/2014

Due Date: 07/18/2014

☒ New License

☐ Amendment

☐ Amended Distribution

License Application	License Number	Fiscal Year	License Type	License Category
A-265-2013	L-277-2014/0	2014	New	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A (b) (4)

Inventors

Inventor's Name	Orig IC	Technologies	Inv Total	Default Inventor %	Alternate Inventor %
(b) (4), (b) (6)	NCI	A	1	25	
	NCI	A	1	25	
	NCI	A	1	25	
	NCI	A	1	25	
Totals:			4	100	

ICs

IC Name	Technologies	IC Total	Default IC %	Alternate IC %
NCI	A	4	100	
Totals:		4	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
1.			
2.			
3.			
4.			

OTT AUTHORIZING OFFICIAL

Whitney Hastings

SIGNATURE

DATE

Whitney A. Hastings -S

6-18-2014

Digitally signed by Whitney A Hastings S
DN: c=US, o=US Government, ou=HHS, ou=NIH, ou=People
09 2342 19200300 100 1 1=0011496767 cn=Whitney A
Hastings S
Date: 2014.06.18 15:10:08 -0400

Jennifer S.
Wong -A

Digitally signed by Jenn for S Wong A
DN: c=US, o=US Government, ou=HHS, ou=NIH
ou=People
09 2342 19200300 100 1 1=0012929897
cn=Jenn for S Wong A
Date: 2014.06.19 12:17:01 -0400

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LICENSE INFORMATION

Generation Date: 10/23/2015

Due Date: 11/22/2015

☐ New License

☒ Amendment

☐ Amended Distribution

License Application	License Number	Fiscal Year	License Type	License Category
A-410-2015	L-277-2014/1		Amendment	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☐ No ☐ Yes

Technologies

Reference No. Lead IC Title

A (b) (4)

Inventors

Inventor's Name	Orig IC	Technologies	Inv Total	Default Inventor %	Alternate Inventor %
(b) (4), (b) (6)	NCI	A	1	25	
	NCI	A	1	25	
	NCI	A	1	25	
	NCI	A	1	25	
Totals:			4	100	

ICs

IC Name	Technologies	IC Total	Default IC %	Alternate IC %
NCI	A	4	100	
Totals:		4	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
1.			
2.			
3.			
4.			

OTT AUTHORIZING OFFICIAL

Whitney Hastings

SIGNATURE Andrew R. Burke
-S (Affiliate)

Digitally signed by Andrew R. Burke -S (Affiliate)
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, o=9.2342.19200300.100.1.1=2000814029, cn=Andrew R. Burke -S (Affiliate)
Date: 2015.10.23 12:26:05 -0400

DATE

ROYALTY DISTRIBUTION FORM

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LICENSE INFORMATION

Generation Date: 04/05/2016

Due Date: 05/05/2016

☐ New License

☒ Amendment

☐ Amended Distribution

License Application	License Number	Fiscal Year	License Type	License Category
A-227-2016	L-277-2014/2	2016	Amendment	Patent-Commercial

Licensee: Kite Pharma, Inc.

Subject to Royalty Sharing Via IIA or Settlement Agr? ☒ No ☐ Yes

Technologies

Reference No. Lead IC Title

A

(b) (4)

Inventors

<u>Inventor's Name</u>	<u>Orig IC</u>	<u>Technologies</u>	<u>Inv Total</u>	<u>Default Inventor %</u>	<u>Alternate Inventor %</u>
(b) (4), (b) (6)	NCI	A	1	25	
	NCI	A	1	25	
	NCI	A	1	25	
	NCI	A	1	25	
Totals:			4	100	

ICs

<u>IC Name</u>	<u>Technologies</u>	<u>IC Total</u>	<u>Default IC %</u>	<u>Alternate IC %</u>
NCI	A	4	100	
Totals:		4	100	

IC DESIGNATION OF RELATIVE SHARES OF ROYALTIES

☐ Default Formula

☐ Alternative Distribution

IC AUTHORIZING OFFICIAL(S)

IC	NAME	SIGNATURE	DATE
1.			
2.			
3.			
4.			

OTT AUTHORIZING OFFICIAL

Andrew R. Burke SIGNATURE DATE

debbie.collins@nih.gov

Digitally signed by debbie.collins@nih.gov
DN: cn=debbie.collins@nih.gov
Date: 2016.04.05 09:24:26 -04'00'



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via email: zack.struver@keionline.org

May 18, 2020

Zack Struver
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009

Re: FOI Case No. 45669

Dear Mr. Struver:

This is the final response to your October 13, 2016, Freedom of Information Act (FOIA) request addressed to the National Cancer Institute (NCI) Freedom of Information (FOIA) Office, National Institutes of Health (NIH), which was forwarded to this office on October 31, 2019. You requested the "Royalty Distribution Form" for all exclusive patent license agreements and Cooperative Research and Development Agreements (CRADAs) between the NCI and Kite Pharma, Inc. In the absence of a "Royalty Distribution Form" for any agreements between Kite and NCI, you request any records which fulfill a similar function, that is, (1) lists the names of employees of the NCI or other NIH components or offices and (2) describes the royalty amounts that those individuals are or will be owed under licensing or R&D agreements.

The National Cancer Institute searched their files and located 28 pages of responsive records. I have determined to withhold portions of those records pursuant to Exemptions 4 and 6 of the FOIA, 5 U.S.C. § 552 (b)(4) and (b)(6), and sections 5.31 (d) and (f) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged and confidential. In this case, the information withheld consists of non-public research. Exemption 6 permits the withholding of privacy information, the release of which would constitute a clearly unwarranted invasion of personal privacy.

You have the right to appeal this determination to deny you access to information in the Agency's possession. Should you wish to do so, your appeal must be sent within ninety (90) days of the date of this letter, following the procedures outlined in Subpart F of the HHS FOIA Regulations (<https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations>) to:

Assistant Secretary for Public Affairs
Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs, Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

Clearly mark both the envelope and your letter “Freedom of Information Act Appeal.”

If you are not satisfied with the processing and handling of this request, you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison

Stephanie Clipper
Public Affairs Specialist
Office of Communications and Public Liaison
Building 1 Room 331
1 Center Drive
Bethesda, MD 20892
301-496-1828 (phone)
nihfoia@mail.nih.gov (email)

OGIS

National Archives and Records Admin.
8601 Adelphi Rd – OGIS
College Park, MD 20740-6001
202-741-5770 (phone)
1-877-684-6448 (toll-free)
202-741-5769 (fax)
ogis@nara.gov (email)

In certain circumstances provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there is no charge associated with our response.

If you have any questions about this response, please call 301-496-5633.

Sincerely,

Gorka Garcia-Malene
Freedom of Information Officer, NIH

Enclosures: 28 pages

45669

FROM: Zack Struver, Knowledge Ecology International
zack.struver@keionline.org

TO: Suzy Milliard, National Cancer Institute FOIA Coordinator, NCIFOIA@mail.nih.gov

DATE: October 13, 2016

RE: Freedom of Information Act Request, Royalty Distribution Forms

Dear Suzy Milliard:

Under the Freedom of Information Act (5 U.S.C. § 552) and relevant Department of Health and Human Services regulations (45 C.F.R. Part 5), Knowledge Ecology International (KEI) requests the "Royalty Distribution Form" for all exclusive patent license agreements and Cooperative Research and Development Agreements (CRADAs) between the National Cancer Institute (NCI) and Kite Pharma, Inc. We believe that the following are the only executed agreements between Kite and the NCI:

- Cooperative Research and Development Agreement No. 02716 (signed by Kite on August 13, 2012)
- License Application No. A-294-2011 (dated April 11, 2013)
- License Application No. A-265-2013 (dated May 22, 2014)
- License Application No. A-563-2014 (December 18, 2014)
- License Application No. A-276-2014 (September 28, 2015)
- Cooperative Research and Development Agreement No. 03019 (dated January 4, 2016)
- Cooperative Research and Development Agreement (dated June 2016)
- License Agreement, dated July 2017
- License Agreement, dated September 2016

If we have not included any licensing agreements or CRADAs in the above list, please also provide the requested form for those other agreements between Kite and the NIH.

Absent the existence of a "Royalty Distribution Form" for any agreements between Kite and NCI, please provide any records which fulfil a similar function, that is, (1) lists the names of employees of the National Cancer Institute or other National Institutes of Health components or offices and (2) describes the royalty amounts that those individuals are or will be owed under licensing or R&D agreements.

Request for Full Waiver of Fees

Knowledge Ecology International (KEI) requests a full waiver of fees under the Freedom of Information Act and under Department of Health and Human Services regulations (45 C.F.R. § 5.45)

Royalty D. Form
or
similar
doc -
Kite

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KEI is a 501(c)(3) non-profit organization that promotes the public interest in ensuring equitable access to affordable medicines.

Congress enacted the current FOIA fee waiver provisions to protect the interests of non-profit public interest groups, such as KEI, that seek to disseminate information that is in the public interest:

"The waiver provision was added to FOIA 'in an attempt to prevent government agencies from using high fees to discourage certain types of requesters and requests,' in a clear reference to requests from journalists, scholars and, most importantly for our purposes, nonprofit public interest groups." *Better Gov't Ass'n v. Department of State*, 780 F.2d 86, 94 (D.C. Cir. 1986) (citations omitted).

Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government.

45 C.F.R. § 5.45(b)(1): How, if at all, do the records to be disclosed pertain to the operations or activities of the Federal Government?

The requested records relate to the operations and activities of the federal government in the administration of royalties on federal patent licenses and Cooperative Research and Development Agreements. These operations and activities include the administration of records and the collection and distribution of royalties to federal employees.

In evaluating this factor, "reasonable specificity" is "all that FOIA requires." *Judicial Watch v. Rossotti*, 326 F.3d 1309, 1313 (D.C. Cir. 2003).

45 C.F.R. § 5.45(b)(2): Would disclosure of the records reveal any meaningful information about government operations or activities? Can one learn from these records anything about such operations that is not already public knowledge?

Disclosure of the requested records is likely to reveal meaningful information about government operations and activities because it will show which federal employees are responsible for the inventions that have been licensed to Kite Pharma, one of the leaders in the development of new and innovative forms of cancer treatment. The information will be meaningful because it will reveal the extent of the relationship between NIH employees and Kite, and the royalty incentives that bear upon NIH employees involved in CRADAs with Kite to ensure successful completion of clinical trials.

The requested records are unique from documents already accessible to the public because neither Kite nor the government has released the Royalty Distribution Form or similar records in relation to agreements between Kite and the NIH. "Legislative history suggests that information

has more of this potential [to contribute to public understanding] to the degree that the information is new and supports public oversight of agency operations, including the effect of agency policy on public health." *McClellan Ecological Seepage Situation v. Carlucci*, 835 F.2d 1282, 1286 (9th. Cir. 1987) (citations omitted).

45 C.F.R. § 5.45(b)(3): Will the disclosure advance the understanding of the general public as distinguished from a narrow segment of interested persons?

Disclosure of the requested record will advance the understanding of the general public as distinguished from a narrow segment of interested persons because KEI has relevant expertise in public health, federal intellectual property rules and law, and NIH licensing procedures, and because the general public has an interest in information on the commercialization of taxpayer-funded inventions.

For example, see:

- a list of stories related to the taxpayer-funded prostate cancer drug, Xtandi, here: <http://keionline.org/node/2451>; and
- various stories on the price of Mylan's EpiPen, which was in part funded through public research: <https://news.google.com/news/story?ncl=d1CTsNNgEKMjIXMi5oAKmTxiJVnVM&q=mylan&lr=English&hl=en&sa=X&ved=0ahUKewihsteuiZ7PAhWM24MKHejgC90QqgllMjAC>

We will provide additional citations upon request.

KEI has expertise in the subject area of the requested records and plans to widely digest and disseminate the requested records to the public. Please see <http://keionline.org/nih-licenses> for our extensive work on licensing procedures at the NIH. Our expertise makes us well suited to analyze and publicize the requested records.

KEI regularly publishes and analyzes records requested under the FOIA on its website:

- 19 September 2016, "500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies," <http://keionline.org/node/2630>
- 16 September 2016, "NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs," <http://keionline.org/node/2629>
- 21 September 2015, "USTR releases documents from 2012 R&D treaty negotiations," <http://keionline.org/node/2325>
- 18 June 2015, "FOIA regarding General Electric's lobbying of USTR to oppose WIPO Treaty for the Blind," <http://keionline.org/node/2254>
- 4 August 2014, "Money speaks: USTR releases letters from Congress backing PhRMA on exclusive rights biologic test data in TPP," <http://keionline.org/node/2069>

- 6 March 2010, "FOIA document: In 2007, US Ambassador Ralph Boyce was pleased that Abbott withdrew life saving drugs from market in Thailand," <http://keionline.org/node/799>

KEI operates a website (<http://keionline.org>) which hosts an extensive archive that is regularly consulted by advocates, academics, and the press. KEI will conduct analysis of the requested records and use social media and listservs to distribute that analysis to a broader public community.

Additionally, KEI works closely with journalists to provide analysis for documents requested by KEI under the FOIA. KEI does not merely distribute documents to journalists, but provides in-depth analysis that later becomes the basis for stories:

- 22 June 2013, Kimberly Kindy, "Filmmakers' group tries to reshape treaty that would benefit the blind," Washington Post
- 24 June 2013, Paige McClanahan, 'US film industry tries to weaken copyright treaty for blind people,' The Guardian
- 24 June 2013, Mike Masnick, "MPAA's Actions, Emails Show That They're Doing Everything Possible To Screw Over The Blind," TechDirt
- 24 June 2013, Catherine Saez, "WIPO Negotiators Reach Breakthrough On '3-Step Test' In Treaty For Blind," IP-Watch

45 C.F.R. § 5.45(b)(4): Will the contribution to public understanding be a significant one? Will the public's understanding of the government's operations be substantially greater as a result of the disclosure?

The contribution to public understanding by disclosure of the requested records will be significant and the public understanding of the government's operations will be substantially greater. NIH currently releases an annual report on technology transfer that only sometimes substantively addresses royalty payments to NIH employees. In 2015, that annual report failed to include even aggregate information on royalty payments to employees. The requested records will deepen the public's understanding of government royalty operations by way of an important example. Kite Pharma is one of the leading pharmaceutical firms in Chimeric Antigen Receptor Therapy (CAR-T), and the requested records pertain to financial incentives that federal employees have to ensure successful commercialization of Kite's inventions under NCI CRADAs. The public understanding will be substantially greater because the public does not generally know which employees at NIH, if any, have substantial financial interest in the successful completion of Kite's clinical trials, which are being conducted by the NCI under the three CRADAs mentioned in our request.

Disclosure is not primarily in the interest of the requestor.

As a 501(c)(3) non-profit organization, KEI plans to use the requested records to broadly educate the public on matters of public interest. KEI does not have any commercial interests in

the records and is not acting on behalf of any other parties. KEI will not use the requested records to further its or others interests in business, trade, and profit, and are not in KEI's commercial interests.

Other

We note that under 45 C.F.R. 5.45(d), that "If the disclosure passes both tests [5.45(a)(1) and (2), as outlined in 5.45(b) and (c)], we will normally waive fees." In accordance with that provision, we request that the FOIA Office waive all fees, rather than reduce fees, if it determines that KEI's request for fee waiver passes both the public interest and commercial interest tests.

Moreover, we note that under 5 U.S.C. § 552(a)(8)(A)(ii), if the NCI FOIA office determines to withhold all records subject to this request, NCI is obligated to: "(I) consider whether partial disclosure of information is possible whenever the agency determines that a full disclosure of a requested record is not possible; and (II) take reasonable steps necessary to segregate and release nonexempt information[.]"

We also request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, and the reasons that the statutory exemption or denial applies in this instance.

If possible, please conduct all correspondence by email and disclose all records via electronic copy. We look forward to your response within 20 days as required by statute.

Please do not hesitate to contact me with any questions. I am happy to clarify the terms of the request or provide additional information in support of our fee waiver.

Thank you.

Sincerely Yours,

Zack Struver
Knowledge Ecology International
zack.struver@keionline.org

1621 Connecticut Ave NW Suite 500
Washington, DC 20009
+1 (202) 332-2670

From: Lampe, Karen (NIH/OD) [E]
Sent: Fri, 6 Mar 2020 18:40:49 +0000
To: Bordine, Roger (NIH/OD) [E]; Garcia-Malene, Gorka (NIH/OD) [E]
Subject: FW: Document requests
Attachments: 45413 - Copy of Request.pdf, 51483 Cassedy.pdf, RE: NHI FOIA Request for Input - Love 46817, Copy of Request 45669 with NIH FOIA notes written.pdf

From: Lampe, Karen (NIH/OD) [E]
Sent: Thursday, January 9, 2020 12:04 PM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: FW: Document requests

Hi Roger,
Gorka asked me to find the case for which I asked you to request further documents from OTT. You'll find the information below for case 51843, which asked for royalty information from 1/1/2010 through present. They've already provided records for August 8, 2011 – August 8, 2016 under request 45413 so they don't need to provide those to us again.

If you have any questions please let me know!

Thanks,
Karen

From: Lampe, Karen (NIH/OD) [E]
Sent: Thursday, January 2, 2020 1:40 PM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: Document requests

Hi Roger,
I'm currently working on the KEI royalties cases (45413, 45669, 46817, 51843 and 51842). Gorka has decided that we can release the names of the employees receiving royalties and so we will need records to review. We have records for 45413. 51483 was a virtually identical request to 45413 but with a different date range. It was closed out last September as a full denial, however we now feel that we need to provide redacted records. We will provide them in response to 45413, but we will need records for the timeframe not covered by the earlier request. To that end, could you please ask OTT to do a search and provide records for 51843? You can let them know that they've done something similar for us already in response to 45413 and that if it is easier, they do not have to provide records already provided. They will need to search for a record that provides an accounting of royalty payments for licensed technologies received by every current or former federal employee for whom the NIH administers royalty payments for, including employees of the NIH, CDC and FDA. The timeframe is January 1, 2010 to the present. They have already provided records for August 8, 2011 – August 8, 2016.

46817 asks for who received royalties from the NIH in 2016. I don't think NIH pays royalties to anyone, do they? It looks like records have been requested for this and you asked for an update in September. Have you heard back?

45669 asks for royalty distribution forms for all license agreements and CRADAs between NCI and KITE Pharma. Could you please ask OTT to also conduct a search for this request?

The final request is for all communications regarding 45413, 45669 and 46817. I think we may wait on this one until we answer the three requests that are the subject of this one but I have to run that past GGM.

Please let me know if you have any questions or need any more information from me.

Thanks,

Karen E. R. Lampe, Ph.D.
Government Information Specialist
NIH Freedom of Information Office (HNA83)
karen.lampe@nih.gov

Bordine, Roger (NIH/OD) [E]

From: Andrew S. Goldman <andrew.goldman@keionline.org>
Sent: Thursday, August 11, 2016 3:35 PM
To: NIH FOIA
Cc: Zack Struver
Subject: FOIA Request re: payment of royalties to current and former employees
Attachments: FOIA-NIH-payment-of-royalties-to-current-and-former-employees.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Ms. Cornell:

Attached, please find a FOIA request regarding (1) any and all records or documents related to individual royalty payments for licensed technologies received by every current or former federal employee for whom the National Institutes of Health (NIH) administers royalty payments for, including employees of the NIH, Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA) between August 8, 2011 and August 8, 2016; and (2) any and all communications and correspondence to or from employees of the NIH, CDC, and FDA that mention the payment of such royalties to current or former individual employees of the NIH, CDC, and FDA between August 8, 2011 and August 8, 2016.

Please let me know if you have any questions or concerns.

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org



2016/493



Ms. Susan R. Cornell
Freedom of Information Officer and Chief FOIA Liaison, NIH
Freedom of Information Office, NIH
Building 31, Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892-2107
nihfoia@mail.nih.gov

August 8, 2016



Dear Ms. Cornell:

Under the Freedom of Information Act (5 U.S.C. § 552), Knowledge Ecology International (KEI) requests (1) any and all records or documents related to individual royalty payments for licensed technologies received by every current or former federal employee for whom the National Institutes of Health (NIH) administers royalty payments for, including employees of the NIH, Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA) between August 8, 2011 and August 8, 2016; and (2) any and all communications and correspondence to or from employees of the NIH, CDC, and FDA that mention the payment of such royalties to current or former individual employees of the NIH, CDC, and FDA between August 8, 2011 and August 8, 2016. These communications may be in the form of emails, briefings, notes, presentations or other formats.

By way of example, the NIH Office of Technology Transfer (OTT) releases an annual report which in part discusses royalty administration, and offers some aggregated figures of royalties administered by OTT as well as aggregated royalties that go to individual inventors.¹ This FOIA request seeks documents that would shed light on those royalty payments in greater detail beyond aggregated numbers. It is possible that these types of more detailed documents and/or records would be found in the OTT.

¹ See, e.g., <https://www.ott.nih.gov/sites/default/files/documents/pdfs/AR2014.pdf> (pp. 11-12).

Knowledge Ecology International requests a complete fee waiver for the requested records under 45 C.F.R. § 5.45. Disclosure of the requested records would be “in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government” (45 C.F.R. § 5.45(a)(1)).

This request for records is in the public interest, and meets the four factors outlined in HHS regulations under 45 C.F.R. § 5.45(b) :

1. The requested records pertain to the operations and activities of the NIH related to its practices of collecting payment of royalties from licensees of inventions to NIH inventors, and distributing those royalty payments to current and former employees of the federal government.
2. Disclosure would reveal meaningful information about NIH operations that are not currently public knowledge by showing with greater detail who in the NIH receives royalties and in what amounts, how NIH OTT officials correspond with federal employees that receive royalties as inventors of federally owned patented inventions, and to what extent such royalty payments play a role in NIH policy-making. Current publicly available information about royalty payments made to NIH inventors — for example, the annual OTT royalty report — is insufficient for a comprehensive understanding of the specific operations and activities related to the administration of royalties in the NIH.
3. The request will broadly advance the understanding of the general public in relation to the relationship of the NIH to licensees, and not just a narrow segment of interested persons. The public has a general interest in understanding to what extent financial and business concerns are affecting the broader decision-making processes at the NIH, particularly with regard to policies involving the transfer of federally-funded technology to the private sector. For example, see news stories in a variety of publications related to the public interest in the development of and royalties on Xtandi, a taxpayer-funded pharmaceutical drug developed with the support of NIH and U.S. Army funds: <http://keionline.org/node/2451>.

In addition, KEI has expertise in the area of royalty rates on pharmaceutical inventions, the research and development process of federally-funded technologies, and licensing practices at the NIH. KEI also has broad experience in distributing and

analyzing FOIA requests in order to provide significantly greater public understanding of issues of public importance, and KEI plans in this case to broadly analyze and disseminate the requested materials with analysis on its website and through the press. KEI regularly publishes and analyzes records requested under the FOIA on its website:

- a. 21 September 2015, "USTR releases documents from 2012 R&D treaty negotiations," <http://keionline.org/node/2325>
- b. 18 June 2015, "FOIA regarding General Electric's lobbying of USTR to oppose WIPO Treaty for the Blind," <http://keionline.org/node/2254>
- c. 6 March 2010, "FOIA document: In 2007, US Ambassador Ralph Boyce was pleased that Abbott withdrew life saving drugs from market in Thailand," <http://keionline.org/node/799>
- d. 4 August 2014, "Money speaks: USTR releases letters from Congress backing PhRMA on exclusive rights biologic test data in TPP," <http://keionline.org/node/2069>

Additionally, KEI works closely with journalists to provide analysis for documents requested by KEI under the FOIA. KEI does not merely distribute documents to journalists, but provides in-depth analysis that later becomes the basis for stories:

- a. 22 June 2013, Kimberly Kindy, "Filmmakers' group tries to reshape treaty that would benefit the blind," Washington Post
 - b. 24 June 2013, Paige McClanahan, 'US film industry tries to weaken copyright treaty for blind people,' The Guardian
 - c. 24 June 2013, Mike Masnick, "MPAA's Actions, Emails Show That They're Doing Everything Possible To Screw Over The Blind," TechDirt
 - d. 24 June 2013, Catherine Saez, "WIPO Negotiators Reach Breakthrough On '3-Step Test' In Treaty For Blind," IP-Watch
4. Disclosure of the requested records will make a significant contribution to public understanding, and the public's understanding will be substantially greater as a result of the disclosure. The disclosure of records and communications on royalty payments will provide important insight into aspects of NIH operations not widely known beyond small segments of the tech community and other interested parties, but which affect all

taxpayers, consumers, and general public. Disclosure would increase public understanding of the aforementioned issues.

Pursuant to the Office of Management and Budget FOIA Fee Guidelines, KEI will provide additional information in support of our fee waiver upon request of the NIH.

As a 501(c)(3) non-profit organization, KEI plans to use the requested records to broadly educate the public on matters of public interest. The records will not be used for interests in business, trade, and profit, and are not in KEI's commercial interests.

We note that under 45 C.F.R. § 5.45(d), that "If the disclosure passes both tests, we will normally waive fees." We request that the NIH FOIA Office waive all fees, rather than reduce fees, because the records will contribute to significant public understanding of government operations and activities.

We are happy to provide more information to support our request for a waiver of FOIA fees and to clarify the terms of this request if needed.

If possible, please provide the FOIA response via electronic copy.

Please address all correspondence relating to this FOIA request to Andrew Goldman and James Love. Thank you for your assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew S. Goldman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Andrew S. Goldman, Esq.
Counsel, Policy and Legal Affairs
Knowledge Ecology International
+1.202.332.2670
andrew.goldman@keionline.org

A handwritten signature in black ink that reads "James Love". The script is fluid and cursive, with the first name "James" and last name "Love" clearly legible.

James Love
Director
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
james.love@keionline.org

Knowledge Ecology International
1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
Tel.: 202.332.2670

FOIA Information Office
Office of Technology Transfer
National Institutes of Health
NIH Building 31, Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892-2107

July 26, 2019

Dear FOIA Officer,

Under the Freedom of Information Act (FOIA), Knowledge Ecology International (KEI) requests the following information, for the period from January 1, 2010 to the present:

- (1) A record that provides an accounting of royalty payments for licensed technologies received by every current or former federal employee for whom the National Institutes of Health (NIH) administers royalty payments for, including employees of the NIH, Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA).
- (2) If (and only if) the NIH is unable or unwilling to generate the record specified in (1), KEI then requests that the NIH provide all documents, communications, and correspondence to or from employees of the NIH, CDC, and FDA that mention the payment of such royalties to current or former employees of the NIH, CDC, and FDA from the same period.

It is our hope that the NIH is able to provide the information in (1), since it seems to be a narrower scope and would require a less extensive search/clearance process than the information in (2).

Request for Full Waiver of Fees

KEI requests a full waiver of fees under the Freedom of Information Act and under DHHS regulations (45 C.F.R. § 5.54).

KEI is a 501(c)(3) non-profit organization that promotes the public interest in ensuring equitable access to affordable medicines.

Congress enacted the current FOIA fee waiver provisions to protect the interests of non-profit public interest groups, such as KEI, that seek to disseminate information that is in the public interest:

“The waiver provision was added to FOIA ‘in an attempt to prevent government agencies from using high fees to discourage certain types of requesters and requests,’ in a clear reference to requests from journalists, scholars and, most importantly for our purposes, nonprofit public interest groups.” *Better Gov’t Ass’n v. Department of State*, 780 F.2d 86, 94 (D.C. Cir. 1986) (citations omitted).

Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not in the commercial interest of the requester.

1. § 5.54(b)(1): *“Disclosure of the requested information would shed light on the operations or activities of the government.”*

Disclosure of the requested records would shed light on the operations and activities of the federal government with regards to setting policy and practice regarding drug research and development, how it licenses technologies it has developed, and how government employees benefit from these policies and practices.

In evaluating this factor, “reasonable specificity” is “all that FOIA requires.” *Judicial Watch v. Rossotti*, 326 F.3d 1309, 1313 (D.C. Cir. 2003).

2. § 5.54(b)(2): *Disclosure of the requested information would be likely to contribute significantly to public understanding of those operations or activities. This factor is satisfied because the following criteria are met.*

2.i. § 5.54(b)(2)(i): *Disclosure of the requested records must be meaningfully informative about government operations or activities.*

Disclosure of the requested records would be meaningfully informative about government operations and activities because it would reveal information that is not yet in the public domain about how the NIH approaches engagement with pharmaceutical companies and sets terms on research products developed using taxpayer funding.

Information concerning royalty payments received by NIH employees is not currently public.

“Legislative history suggests that information has more of this potential [to contribute to public understanding] to the degree that the information is new and supports public oversight of agency operations, including the effect of agency policy on public health.” *McClellan Ecological Seepage Situation v. Carlucci*, 835 F.2d 1282, 1286 (9th. Cir. 1987) (citations omitted).

2.i. § 5.54(b)(2)(ii): The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester.

The subject of the request is government operations and activities related to the R&D of government funded technologies and how they are licensed to private industry, and how that impacts the price of prescription drugs in the United States.

There is a broad audience of persons interested in the subject, including, inter alia, advocates for affordable access to medicines; public health researchers, doctors, nurses, and other medical providers; patients and caretakers; policy experts; and people who purchase insurance or other forms of medical care. Disclosure would contribute to the understanding of that broad audience of persons because it would provide context for the policies, positions, and decisions of the National Institutes of Health related to medical R&D, access to medicines and drug pricing.

KEI is an NGO that works on drug pricing and access to medicines, and has expertise in public health, drug pricing, and access to medicines.

KEI has the ability and intention to effectively convey the information contained in the requested records to the public. KEI operates a website (<https://keionline.org>) which hosts an extensive archive that is regularly consulted by advocates, academics, and the press. KEI will review the requested records and produce a clear and concise analysis of those records. KEI will use social media and listservs to distribute that analysis to the broad audience of persons interested in the subject of the request.

KEI regularly publishes and analyzes records requested under the FOIA on its website, including recently on various government operations and activities at parts of DHHS:

- 29 November 2018, "Pfizer's efforts to block Colombia's accession to the OECD in 2017-2018," <https://www.keionline.org/29289>
- 28 November 2018, "Communications between Gilead and USTR regarding Malaysia compulsory license on HCV patents, 2017 to May 2018," <https://www.keionline.org/29257>
- 8 June 2017, "FOIA documents: In 2015 Novartis asked US Dept of Commerce to Pressure Colombia Against Compulsory License on Glivec," <https://www.keionline.org/23372>
- 28 February 2017, "CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB," <https://keionline.org/node/2727>
- 18 October 2016, "Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments," <https://keionline.org/node/2640>
- 19 September 2016, "500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies," <https://keionline.org/node/2630>

- 16 September 2016, "NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs," <https://keionline.org/node/2629>

A comprehensive list of KEI's publication of records received via FOIA request can be accessed on our website at: <https://www.keionline.org/foia>

Additionally, KEI works closely with journalists to provide analysis for documents requested by KEI under the FOIA. KEI regularly advises and is cited by major outlets such as the New York Times ("[Trump's Proposed Budget Undermines His HIV Plan, Experts Say](#)," 12 March 2019) and the Washington Post ("[A rare deterrent to limitless drug price increases may die under Trump](#)," 17 April 2019). KEI does not merely distribute documents to journalists, but provides in-depth analysis that later becomes the basis for stories:

- 13 February 2019, William New, "Malaysia Still Under Pressure To Make Hepatitis C Medicine More Expensive," <https://www.ip-watch.org/2019/02/13/malaysia-still-pressure-make-hepatitis-c-medicine-expensive/>
- 12 February 2019, Loh Foon Fong, "Medical aid group MSF supports Malaysia's compulsory licensing stance," <https://www.thestar.com.my/news/nation/2019/02/12/medical-aid-group-msf-supports-malaysias-compulsory-licensing-stance/>
- 3 March 2017, Vidya Krishnan, "U.S. nixed India's plea on reforms in medicine," The Hindu, <http://www.thehindu.com/news/national/us-nixed-indias-plea-on-reforms-in-medicine/article17403526.ece>
- 31 December 2016, Dan Vergano, "If Taxpayers Invent A Drug, Should The Government Just Give It Away?," BuzzFeed News, <https://www.buzzfeed.com/danvergano/nih-drug-giveaway>
- 19 December 2016, Matt Richtel and Andrew Pollack, "Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits," <https://www.nytimes.com/2016/12/19/health/harnessing-the-us-taxpayer-to-fight-cancer-and-make-profits.html>

3. § 5.54(b)(3): *The disclosure must not be primarily in the commercial interest of the requester.*

Knowledge Ecology International is a non-profit 501(c)(3) organization that does not have any commercial, trade, or profit interest in disclosure of the requested records.

Other

We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons

that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record.

We look forward to your acknowledgement of this request within 10 working days and your final determination within 20 working days. 5 U.S.C. § 552(a)(6)(A)(i). Please inform us of any unusual circumstances that would require you to extend the 20-day statutory time limit, "setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched." 5 U.S.C. § 552(a)(6)(B)(i).

If possible, please conduct all correspondence by email and disclose all records via electronic copy. Please contact me if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver. Thank you in advance for your assistance.

Sincerely,
Claire Cassedy
claire.cassedy@keionline.org

From: Garcia-Malene, Gorka (NIH/OD) [E]
Sent: Mon, 9 Mar 2020 18:30:34 +0000
To: Bordine, Roger (NIH/OD) [E]
Cc: Lampe, Karen (NIH/OD) [E]
Subject: FW: Document requests

Hi Roger,

Did this go out?

From: Garcia-Malene, Gorka (NIH/OD) [E]
Sent: Friday, March 6, 2020 1:42 PM
To: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>; Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: RE: Document requests

Thanks, Karen.

Roger: Have we received records for what Karen just sent?

From: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Sent: Friday, March 6, 2020 1:41 PM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>; Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Subject: FW: Document requests

From: Lampe, Karen (NIH/OD) [E]
Sent: Thursday, January 9, 2020 12:04 PM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: FW: Document requests

Hi Roger,

Gorka asked me to find the case for which I asked you to request further documents from OTT. You'll find the information below for case 51843, which asked for royalty information from 1/1/2010 through present. They've already provided records for August 8, 2011 – August 8, 2016 under request 45413 so they don't need to provide those to us again.

In short, these are still pending at OTT: 45669, 46817, 51843

If you have any questions please let me know!

Thanks,
Karen

From: Lampe, Karen (NIH/OD) [E]
Sent: Thursday, January 2, 2020 1:40 PM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: Document requests

Hi Roger,

I'm currently working on the KEI royalties cases (45413, 45669, 46817, 51843 and 51842). Gorka has decided that we can release the names of the employees receiving royalties and so we will need records to review. We have records for 45413. 51483 was a virtually identical request to 45413 but with a different date range. It was closed out last September as a full denial, however we now feel that we need to provide redacted records. We will provide them in response to 45413, but we will need records for the timeframe not covered by the earlier request. To that end, could you please ask OTT to do a search and provide records for 51843? You can let them know that they've done something similar for us already in response to 45413 and that if it is easier, they do not have to provide records already provided. They will need to search for a record that provides an accounting of royalty payments for licensed technologies received by every current or former federal employee for whom the NIH administers royalty payments for, including employees of the NIH, CDC and FDA. The timeframe is January 1, 2010 to the present. They have already provided records for August 8, 2011 – August 8, 2016.

46817 asks for who received royalties from the NIH in 2016. I don't think NIH pays royalties to anyone, do they? It looks like records have been requested for this and you asked for an update in September. Have you heard back?

45669 asks for royalty distribution forms for all license agreements and CRADAs between NCI and KITE Pharma. Could you please ask OTT to also conduct a search for this request?

The final request is for all communications regarding 45413, 45669 and 46817. I think we may wait on this one until we answer the three requests that are the subject of this one but I have to run that past GGM.

Please let me know if you have any questions or need any more information from me.

Thanks,

Karen E. R. Lampe, Ph.D.
Government Information Specialist
NIH Freedom of Information Office (HNA83)
karen.lampe@nih.gov

From: Garcia-Malene, Gorka (NIH/OD) [E]
Sent: Fri, 3 Jan 2020 18:21:21 +0000
To: Thomas, Gina (NIH/OD) [E]; Glasford-Clarke, Margaret (NIH/OD) [E]
Cc: Goldstein, Bruce (NIH/NHLBI) [E]
Subject: FW: FOIA Question for OTT
Attachments: 45413 - Copy of Request.pdf

Sorry for the mistake: I meant to send this to Gina, not Margaret.

Thank you!

Gorka

From: Garcia-Malene, Gorka (NIH/OD) [E]
Sent: Friday, January 3, 2020 1:19 PM
To: Glasford-Clarke, Margaret (NIH/OD) [E] <glasfordm@mail.nih.gov>
Cc: NIH FOIA <nihfoia@od.nih.gov>; Goldstein, Bruce (NIH/NHLBI) [E] <goldsteb@mail.nih.gov>; Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: FOIA Question for OTT

Good afternoon, Margaret –

Happy New Year!

I have a brief question about the records OTT provided on request 45413 (request is attached). Specifically, we would appreciate OTT's view on the release of the names of licensees. We are concerned that release of these name may inadvertently disclose a company's business plans to move into a research/development space, particularly in cases where the license may not have resulted from a CRADA.

What is your position on release of the licensee name? It may be that it is accepted that these names are releasable regardless. Your insight would be greatly appreciated.

Gorka Garcia-Malene
FOIA Officer for the National Institutes of Health | (301) 496-5633

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wed, 6 May 2020 17:40:52 +0000
To: Lampe, Karen (NIH/OD) [E]
Subject: FW: KEI request 45669

(b)(4)

(b)(4)

From: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Sent: Wednesday, May 6, 2020 11:07 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Subject: KEI request 45669

Good morning Mark,

Attached are royalty distribution forms responsive to request 45669 (also attached). They've been boxed as OTT has redacted them in the past. Please review and let me know if you see anything that needs to be changed before we apply the redactions and release to KEI.

Thanks,

Karen E. R. Lampe, Ph.D.
Government Information Specialist
NIH Freedom of Information Office (HNA83)
karen.lampe@nih.gov

From: NIH FOIA
Sent: Fri, 28 Aug 2020 16:46:13 +0000
To: Gee, Karen (NIH/OD) [E]
Subject: FW: New FOIA Appeal 2020-00288-A-PHS, Kathryn Ardizzone
Attachments: FOIA Appeal Case No. 45669 2020-00288-A-OS.msg, Notice of Appeal_2020-00288-A-PHS NIH.docx

Good Afternoon Karen,

Please see the attached and below appeal.

Thank you, and Happy Friday Karen!

- Roger

From: Trent, Jacqueline <foiarequest@hhs.gov>
Sent: Friday, August 28, 2020 12:32 PM
To: NIH FOIA <nihfoia@od.nih.gov>
Cc: Lancey, Brandon (OS/ASPA) <Brandon.Lancey@hhs.gov>
Subject: New FOIA Appeal 2020-00288-A-PHS, Kathryn Ardizzone

Request for Documents for Request # '2020-00288-A-PHS'. Your response due date is: 9/4/2020 12:00:00 AM
Message from SENDER:

Dear NIH FOIA Office,

Attached is a new FOIA appeal **2020-00288-A-PHS, Kathryn Ardizzone**. In order to assist our office in successfully processing this appeal, please provide the following back to the PHS FOIA office:

- Initial FOIA request letter
- Any other correspondence received from the FOIA requester/appellant
- Your office/agency response letter(s) (i.e partial, interim, final)
- All withheld information or records (clean and boxed (transparent redacted) versions)

If you have any questions regarding this appeal, please e-mail FOIARquest@psc.hhs.gov.

Sincerely,

Brandon Lancey

From: kathryn ardizzone
Sent: Wed, 19 Aug 2020 13:32:03 -0400
To: OS FOIA Request (HHS/ASPA)
Cc: James Love; Claire Cassedy
Subject: FOIA Appeal , Case No. 45669
Attachments: KEI FOIA Appeal 8.19.2020, FOIA Case No. 45669.pdf

Dear FOIA Officer:

Attached, please find KEI's administrative appeal to FOIA Case No. 45669. Please do not hesitate to let me know if you require any additional information regarding this appeal. We look forward to your response within 20 working days, as required by the Freedom of Information Act.

Sincerely,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670



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Suite 500
Washington, DC 20009
www.keionline.org

August 19, 2020

Assistant Secretary for Public Affairs
Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs, Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201
Via Email: FOIARequest@hhs.gov

Re: Freedom of Information Act Appeal, Case No. 45669

Dear FOIA Appeals Officer:

By letter dated May 21, 2020, the National Institutes of Health (NIH) issued its final response to the Freedom of Information Act (FOIA) request submitted by Knowledge Ecology International (KEI) on October 13, 2016 (Case No. 45669), which asked for “the ‘Royalty Distribution Form’ for all exclusive patent license agreements and Cooperative Research and Development Agreements (CRADAs) between the National Cancer Institute (NCI) and Kite Pharma, Inc.” The final response letter enclosed 28 pages of responsive records, with information redacted under Exemptions 4 and 6 of the FOIA.

KEI hereby appeals this initial determination. As demonstrated below, the redacted information is not protected under Exemption 4 or 6 because it consists of publicly-available information generated from within the NIH, for which there is no legitimate confidentiality or privacy interest.

Background

On October 13, 2016, KEI submitted a FOIA request seeking copies of the Royalty Distribution Forms for all license agreements and Cooperative Research and Development Agreements between the National Cancer Institute (NCI) and Kite Pharma, Inc. (“Kite”).

After much back and forth and more than three years’ delay, the NIH finally provided KEI with a final response letter and responsive records on May 21, 2020.

The final response letter states that the NCI located 28 pages of responsive records and was redacting parts of those records under Exemptions 4 and 6 of the FOIA. With regard to Exemption 4, the letter states that the redacted materials consist of “non-public research.” Concerning Exemption 6, the letter states that the exemption “permits the withholding of privacy information, the release of which would constitute a clearly unwarranted invasion of personal privacy.” The letter does not explain how release of the information redacted under Exemption 6 would cause such an invasion.

The information redacted under Exemption 4 on the Royalty Distribution Forms consists of the Technologies “Reference No.,” “Lead IC,” and Title, and inventors’ names for each of the licensed technologies. The inventors’ names are also redacted under Exemption 6.

The NIH wrongly redacted responsive information under Exemptions 4 and 6 of the FOIA.

The purpose of the FOIA is to “‘pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny.’” *Morley v. C.I.A.*, 508 F.3d 1108, 1114 (D.C. Cir. 2007)(citing *Dep’t of Air Force v. Rose*, 425 U.S. 352, 361 (1976)). To that end, “[the] FOIA mandates a strong presumption in favor of disclosure, and . . . the statutory exemptions, which are exclusive, are to be narrowly construed.” *Nat’l Ass’n of Home Builders v. Norton*, 309 F.3d 26, 32 (D.C. Cir. 2002)(internal quotation marks and citation omitted). “[T]hese limited exemptions do not obscure the basic policy that disclosure, not secrecy, is the dominant objective of the Act.” *Dep’t of the Air Force v. Rose*, 425 U.S. 352, 361 (1976).

As a result of the FOIA Improvement Act of 2016, an agency may not withhold responsive information simply because it satisfies the criteria for a FOIA exemption. Rather, the agency must also demonstrate that disclosure of the exempt information will cause reasonably foreseeable harm to an interest protected by the exemption or that disclosure is prohibited by law. 5 U.S.C. § 552(a)(8)(A)(i). This is an “independent and meaningful burden.” *Ctr. for Investigative Reporting v. U.S. Customs & Border Prot.*, 436 F. Supp. 3d 90, 106 (D.D.C. 2019).

To establish reasonably foreseeable harm, an agency must “‘identify specific harms to the relevant protected interests that it can reasonably foresee would actually ensue from disclosure of the withheld materials’ and ‘connect[] the harms in [a] meaningful way to the information withheld.’” *Id.* “In the context of Exemption 4, this ‘foreseeable harm’ requirement replaces to some extent the ‘substantial competitive harm’ test that the Supreme Court overruled in *Food Marketing*.” *Id.* at 113. “To meet this requirement, [the agency] must explain how disclosing, in whole or in part, the specific information withheld under Exemption 4 would harm an interest protected by this exemption, such as by causing genuine harm to [the submitter’s] economic or business interests, and thereby dissuading others from submitting similar information to the government.” *Id.* (internal quotation and citation omitted).

The redactions in the responsive records improperly withhold information under Exemptions 4 and 6 of the FOIA, when the redacted material does not satisfy the criteria for those exemptions.

1. The Reference Nos., Lead ICs, Titles, and inventors' names for the licensed inventions are not protected by Exemption 4 of the FOIA because they were not obtained from a company, are not commercial information, and are not confidential.

Exemption 4 of the FOIA protects from disclosure “trade secrets and commercial or financial information obtained from a person” that is “privileged or confidential.” 5 U.S.C. § 552(b). Information is confidential if it is “[1] customarily and actually treated as private by its owner and [2] provided to the government under an assurance of privacy.” *Food Mktg Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019).

For several reasons, none of the information withheld under Exemption 4 satisfies the criteria for that exemption.

As a threshold matter, none of the redacted information was obtained from a person (or company). The inventions described in the Royalty Distribution forms were conceived of by *NIH* scientists in *NIH* laboratories, and presumably were assigned titles and reference numbers by the NIH. The identity of an NIH employee cannot, for obvious reasons, be thought to emanate from a person or company. Because the redacted information was generated by the NIH, it is not protected by Exemption 4.

Even if the information was obtained from outside the NIH, the redacted information still would not be protected from disclosure under Exemption 4, as it is neither confidential, nor “non-public research”.

For information to be confidential, it must at least be closely held by its source. However, Kite does not customarily or actually treat information about its licenses and CRADAs with the NCI (including descriptions of the licensed technologies) confidential.

Annex 1 demonstrates several examples of how Kite has publicly-disclosed detailed information about its licenses with the NCI, in its filings with the Securities and Exchange Commission (SEC). As demonstrated by the excerpts, Kite revealed granular information about the licenses, such as their duration, the nature of the covered inventions, the grounds for termination, and royalty payment terms. Because Kite has publicly disclosed information about its licenses in such granular detail, including the nature of the covered inventions, this information is not confidential.

Furthermore, as a result of the NIH’s own disclosures, the redacted information is in the public domain and thus non-confidential. See *Niagara Mohawk Power Corp. v. DOJ*, 169 F.3d 16, 19 (D.C. Cir.1999).

The NIH OTT website contains a *Find Technologies* search engine that is searchable by Ref. No., key terms, and inventor name, among other fields. Searches yield abstracts of inventions developed by NIH scientists. The abstracts contain the reference number, inventors’ names, institutional centers, patent and patent application numbers, scientific articles describing the invention, and other information related to NIH-owned inventions available for licensing. The abstracts for each invention can also be located at <https://www.ott.nih.gov/opportunities>, where they are listed by number and title.

The NIH also publicly discloses information about publicly-owned technologies when it provides public notice of prospective exclusive prospective licenses, as required by 35 U.S.C. § 209(e). From KEI's experience commenting on at least 40 such licenses, the NIH notices, which are published in the Federal Register, generally disclose the name of the prospective licensees, the reference number for the covered inventions, the numbers of the relevant patents or patent applications, and descriptions of the inventions. This is the same information that the NIH redacted under Exemption 4. Yet, as noted above, because the information is in the public domain, it is not protected by that, or any other, FOIA exemption.

Nor can the NIH demonstrate that disclosure of the redacted materials would harm an interest protected by Exemption 4. We know of at least nine examples of Federal Register notices publicly describing proposed exclusive patent licenses to Kite, and the notices listed the subject inventions' reference numbers, titles, and patent or patent application numbers, which can easily be utilized to locate the inventors' names. The only information concerning the licenses that the NIH has not made public is whether or not they were executed. This information could be indirectly disclosed by the unredacted records. However, there is no reason to believe that such information would harm Kite's confidential commercial or financial interests. The notices include a disclaimer that the licenses may be granted unless the NIH receives evidence demonstrating that the licenses are unlawful. The fact that it is public knowledge that the licenses would likely be granted to Kite means that there is no reasonably foreseeable harm from indirectly disclosing the fact that they were executed. More fundamentally to the criteria for Exemption 4, Kite's SEC disclosures and past press releases provide detailed information about its executed licenses with NIH, making that information nonconfidential. In 2016, KEI published a blog at <https://www.keionline.org/23173> listing news articles and press releases (including press releases issued by Kite) regarding Kite's exclusive licenses with the NIH.

Table 1 lists examples of Federal Register notices of Prospective Exclusive Patent Licenses from the NIH to Kite. The inventor names can be located using the NIH OTT webpage or U.S.P.T.O. search engines.

Table 1, Federal Register Notices Issued by the NCI Reveal the Invention Titles, Reference Numbers, and Institutional Center (NCI)

<u>Date</u>	<u>Notice Title, URL, Invention Ref. No, Invention Title, and Institutional Center</u>
7/12/2019	<i>Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20 and Prospective Grant of an Exclusive Patent License: Autologus Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20</i> <u>Links:</u> https://www.federalregister.gov/documents/2019/07/12/2019-14822/prospective-grant-of-an-exclusive-patent-license-allogeneic-therapy-using-bicistronic-chimeric https://www.federalregister.gov/documents/2019/07/12/2019-14823/prospective-grant-of-an-exclusive-patent-license-autologus-therapy-using-bicistronic-chimeric

	<u>Invention</u>: Ref. No. E-205-2018, “Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20 and Their Uses” <u>Institutional Center</u>: NCI
12/20/2017	<i>Prospective Grant of an Exclusive Patent License: The Development of an Anti-CD30 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer</i> <u>Link</u>: https://www.federalregister.gov/d/2017-27416 <u>Invention</u>: Ref. No. E-016-2018, “Anti-CD30 Chimeric Antigen Receptors” <u>Institutional Center</u>: NCI
10/05/2016	<i>Prospective Grant of Exclusive Patent License: Development of Anti-CD70 Chimeric Antigen Receptors for the Treatment of CD70 Expressing Cancers</i> <u>Link</u>: https://www.federalregister.gov/d/2016-24030 <u>Invention</u>: Ref. No. E-021-2015, “Anti-CD70 Chimeric Antigen Receptors” <u>Institutional Center</u>: NCI
08/17/2016	<i>Prospective Grant of Exclusive Patent License: Development of T Cell Receptors (TCRs) Targeting the KRAS G12D Mutation for the Treatment of Cancer</i> <u>Link</u>: https://www.federalregister.gov/d/2016-19549 <u>Invention</u>: Ref. No. E-028-2015, “Anti-mutated KRAS T Cell Receptors”
06/26/2015	<i>Prospective Grant of Exclusive License: The Development of an Anti-CD19 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancers</i> <u>Link</u>: https://www.federalregister.gov/d/2015-15657 <u>Inventions</u>: Ref. No. E-042-2014, “Chimeric Antigen Receptors Targeting CD-19” <u>Institutional Center</u>: NCI
10/16/2014	<i>Prospective Grant of Exclusive License: Development of T Cell Receptors for Adoptive Transfer in Humans To Treat Cancer</i> <u>Link</u>: https://www.federalregister.gov/d/2014-24502 <u>Invention</u>: Ref Nos. E-230-2012, “T Cell Receptors Recognizing MCH Class II-Restricted Mage-A3”; E-266-2011, “T cell receptors recognizing HLA-A1 or HLA-Cw7 restricted MAGE” <u>Institutional Center</u>: NCI
03/25/2014	<i>Prospective Grant of Exclusive License: Development of T Cell Receptors for Adoptive Transfer in Humans to Treat Cancer</i> <u>Link</u>: https://www.federalregister.gov/d/2014-06412 <u>Invention</u>: Ref No. E-105-2012, “Murine anti-NY-ESO-1 T cell receptors” <u>Institutional Center</u>: NCI

01/24/2012	<i>Prospective Grant of Exclusive License: Development of T Cell Receptors and Chimeric Antigen Receptors Into Therapeutics for Adoptive Transfer in Humans To Treat Cancer</i> <u>Link:</u> https://www.federalregister.gov/d/2012-1383 <u>Inventions:</u> Ref. Nos. E-236-2010, “Anti-MAGE-A3 T cell receptors and related materials and methods of use”; E-269-2010, “Anti-SSX-2 T cell receptors and related materials and methods of use”; E-148-2011, “Anti-epidermal growth factor receptor variant III chimeric antigen receptors and use of same for the treatment of cancer”; and E-266-2011, “T cell receptors recognizing HLA-A1- or HLA-Cw7-restricted MAGE-A”. <u>Institutional Center:</u> NCI
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In addition to the fact that the employee-inventor names are publicly-available, District of Columbia courts typically do not regard the names of agency employees as commercial information within the meaning of FOIA Exemption 4, disqualifying it for the exemption. *See Besson v. United States Dep't of Commerce*, No. 18-CV-02527 (APM), 2020 WL 4500894, at *3 (D.D.C. Aug. 5, 2020) (listing D.C. cases in which employees' names were found to be non-exempt from disclosure under Exemption 4 of the FOIA).

2. *Disclosures of the names of NCI employees who conceived of NIH-owned inventions would not constitute a clearly unwarranted invasion of personal privacy, and there is a strong public interest in knowing how the NIH performs its duties in negotiating exclusive licenses to publicly-owned technologies.*

The names of NCI employees who invented the technologies were wrongly withheld under Exemption 6 of the FOIA, which allows agencies to withhold “personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.” 5 U.S.C. § 552(b)(6).

To determine whether disclosure would constitute “a clearly unwarranted invasion of personal privacy” requires “balancing between each censured employee's interest in privacy and the public's interest in disclosure.” *Stern v. F.B.I.*, 737 F.2d 84, 91 (D.C. Cir. 1984). In conducting this balancing, courts are mindful that “under Exemption 6, the presumption in favor of disclosure is as strong as can be found anywhere in the [Freedom of Information] Act.” *See Multi Ag Media LLC v. USDA*, 515 F.3d 1224, 1227 (D.C. Cir. 2008)(quotation omitted). “Because the basic purpose of [FOIA] ... focuses on the citizens' right to be informed about what their government is up to, information that sheds light on an agency's performance of its statutory duties is in the public interest.” *Id.* at 1231 (quotations omitted).

The threshold issue under Exemption 6 is whether the record at issue constitutes “personnel and medical files [or] similar files”. The fact that a record mentions a federal employee’s name does not mean this element is satisfied. For example, the United States District Court for the District of Columbia held that records containing the names and telephone numbers of employees of the Department of Justice were not

“similar to a ‘personnel’ or ‘medical’ file,” reasoning that “[a] name and work telephone number is not personal or intimate information, such as a home address or a social security number, that normally would be considered protected information under FOIA Exemption 6.” *See Leadership Conference on Civil Rights v. Gonzales*, 404 F. Supp. 2d 246, 257 (D.D.C. 2005). Here, because the information redacted under Exemption 6 consists solely of NCI employees’ names and no sensitive, closely-held personal identifier such as a social security number or home address, it does not satisfy “the threshold requirement of Exemption 6.” *See id.*

Even if the threshold requirement were satisfied, the redacted information still would not be shielded by Exemption 6, because there is no privacy interest in the names of NIH employee-inventors, and a strong public interest in understanding how NIH employees benefit financially from the NIH’s partnerships with outside companies.

It is no secret that the inventors whose names are redacted in the responsive records are scientists employed with the NIH—such information can be located at the NIH’s website. More to the point, it is not a secret that an NIH employee is associated with a particular invention. The invention abstracts published by the NIH OTT list the inventors who conceived of a particular invention, and that information is also publicly disclosed in the patent application or patent texts, which are available for inspection at public databases such as the U.S. P.T.O. Patent Full-Text and Image Database (PatFt). Nor is there a compelling privacy interest in the fact that an NIH employee receives a royalty payment for inventing a licensed technology.

This information reveals nothing about the employee’s personal affairs—the privacy interest that is protected by Exemption 6. It is, however, directly related to his or her role as a public employee. Further, the fact that NIH scientists receive royalty payments for their inventions conceived of during their employment with the NIH is public knowledge. Detailed information about the royalty payments to NIH scientists is disclosed at <https://www.ott.nih.gov/royalty/information-nih-inventors#1>, such as the following excerpt:

Inventors receive the first \$2,000 collected from a licensee. Next, they receive 15 percent of royalties above \$2,000 and up to \$50,000. Finally, they receive 25 percent of royalties in excess of the first \$50,000 collected each year. Each inventor cannot receive more than \$150,000 in royalty payments for a calendar year.¹

Additionally, there can be no privacy interest in how a federal employee is compensated for activities that fall within the scope of his or her employment for the federal government, as federal employees’ salaries are in the public domain. *See* 5 C.F.R. § 293.311 (making public federal employees’ names, present and past position titles, and present and past annual salary rates (including performance awards or bonuses, incentive awards, merit pay amount, Meritorious or Distinguished Executive Ranks, and allowances and differentials), among other employment-related matters). For this reason, the United States District Court for the District of Columbia held that information related to a federal employee’s salary was not exempt

¹ *Id.*

under Exemption 6 of the FOIA. *See Parker v. U.S. Dep't of Justice*, 986 F. Supp. 2d 30 (D.D.C. 2013). There is no appreciable difference between an employee's performance awards or bonuses and their royalty payments. As such, the information can be disclosed without causing a clearly unwarranted invasion of personal privacy to any of the employee-inventors.

In contrast, the public interest in disclosure is strong. As noted above, the relevant public interest in disclosure under the FOIA concerns the extent to which disclosure will shed light on how a federal agency is performing its functions. Exclusive licenses to federally-owned inventions are governed by the conditions set forth at 35 U.S.C. § 209. Executing such licenses is thus a function of the NIH, as the NIH must consider public comment and ensure that the criteria listed at 35 U.S.C. § 209 are satisfied. There is an interest in knowing how the NIH performs its duties in negotiating licenses to federally-owned inventions, as the exclusive licenses result in monopolies over publicly-funded technologies that can lead to higher prices and restricted access.

The extent to which NIH employees are compensated for licenses to technologies they invent in their role as NIH scientists is relevant to whether financial interests may play any role in the terms of the licenses, and, by extension, whether or not the NIH is performing its duties under 35 U.S.C. § 209.

The public's interest in the issue at hand is demonstrated by the 2016 front-page, *New York Times* article exploring the relationship between NCI inventor Steven Rosenberg and Kite, and the implications for taxpayers, and federally-funded inventions, titled "Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits."² More generally, investment in biomedical research, exclusivities over taxpayer-funded inventions, and the federal government's performance in protecting taxpayers' investments in biomedical research have generated significant public attention recently, as the high cost of prescription medicines and appropriate legislative solutions are some of the most important issues to voters.

Conclusion

We have demonstrated how the information in the records produced by the NIH in response to Case No. 45669 was improperly redacted under Exemptions 4 and 6 of the FOIA. Because the NIH committed plain error, its initial determination must be reversed, and it must provide the responsive records with no redactions.

HHS must respond to this appeal within 20 days. *See* 5 U.S.C. § 552(a)(6)(A)(ii). We look forward to your response. If you have any questions regarding this appeal, please contact me directly at kathryn.ardizzone@keionline.org.

² Matt Richtel and Andrew Pollack, "Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits" *N.Y. TIMES* (Dec. 19, 2016), <https://www.nytimes.com/2016/12/19/health/harnessing-the-us-taxpayer-to-fight-cancer-and-make-profits.html>.

Sincerely,

Kathryn Ardizzone

Counsel

Knowledge Ecology International

1621 Connecticut Ave NW, Suite 500

Washington, DC 20009

+1.401.369.5433

ANNEX 1

NIH Licenses Referenced in Kite Pharma SEC 10-K Forms

2013 NIH License Agreement³

“Pursuant to a patent license agreement with the NIH, dated April 11, 2013, the Company holds an exclusive, worldwide license to certain intellectual property, including intellectual property related to a CAR-based product candidate that targets the EGFRvIII antigen for the treatment of brain cancer and head and neck cancer, and a TCR-based product candidate that targets the SSX2 CTA for the treatment of head and neck cancer, hepatocellular carcinoma, melanoma, prostate cancer, and sarcoma. The Company has a co-exclusive license to intellectual property related to these product candidates for the treatment of certain other cancers. The Company may require an additional license relating to the EGFRvIII scFv target binding site from a third-party in order to commercialize a CAR-based product candidate that targets the EGFRvIII antigen.”

“Pursuant to the terms of the NIH License, the Company paid the NIH one-time cash payments in the aggregate amount of \$200,000. The Company reimbursed the NIH for past patent expenses in the aggregate amount of approximately \$58,000, with half of this amount paid during 2013 and the balance paid in May 2014.”

“The Company is also required to pay the NIH minimum annual royalties in the amount of \$20,000. The first minimum annual royalty payment is payable on the date that is 60 days following the expiration of the 2012 CRADA, and thereafter shall be payable on each January 1st.”

“The Company is also required to make performance-based cash payments upon successful completion of clinical and regulatory benchmarks relating to the products covered by the NIH license (the “Licensed Products”). The aggregate potential clinical and regulatory benchmark payments for each Licensed Product are \$4.0 million, of which \$3.0 million is due only after marketing approval in the United States, Europe, Japan, China or India. The first benchmark payment of \$50,000 will be due upon the commencement of the first company sponsored human clinical study of a Licensed Product in the United States.”

“In addition, the Company must also pay the NIH royalties on net sales of Licensed Products at rates in the mid-single digits. The Company is also required to pay NIH benchmark payments based upon aggregate net sales of Licensed Products, which amount will equal up to \$7.0 million

³ https://www.sec.gov/Archives/edgar/data/1510580/000156459016013699/kite-10k_20151231.htm Page 88

following aggregate net sales of \$1.0 billion. To the extent the Company enters into a sublicensing agreement relating to the Licensed Products, the Company is required to pay the NIH a percentage of all consideration received from a sublicensee, which percentage will decrease based on the stage of development of the Licensed Products at the time of the sublicense. Pursuant to an amendment dated October 1, 2015, any such sublicense payment will be subject to a cap.”

“The license will expire upon expiration of the last patent contained in the licensed patent rights, unless terminated earlier. None of the applications included in the NIH licensed patent rights have issued yet. Any patents issuing from these applications will have a base expiration date no earlier than 2031. The NIH may terminate or modify the NIH license in the event of a material breach, including if the Company does not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. The Company may terminate the license, or any portion thereof, at its sole discretion at any time upon 60 days written notice to the NIH. In addition, the NIH has the right to require the Company to sublicense the rights to the product candidates covered by this license upon certain conditions, including if the Company is not reasonably satisfying required health and safety needs or if the Company is not satisfying requirements for public use as specified by federal regulations.”

“The expenses recognized under the NIH license were \$196,484, \$90,000 and \$191,200 for the years ended December 31, 2015, 2014 and 2013, respectively.”

May 2014 NIH License Agreement⁴

“Pursuant to a patent license agreement with the NIH, dated May 29, 2014, we hold an exclusive, worldwide license to certain intellectual property related to TCR-based product candidates that target the NY-ESO-1 antigen for the treatment of any NY-ESO-1 expressing cancers. As of the date of the license, NY-ESO-1 expressing tumors can be found in the following cancers: sarcoma, urothelial carcinoma, esophageal carcinoma, non-small cell lung cancer, breast carcinoma, ovarian carcinoma, prostate carcinoma, multiple myeloma, hepatocellular carcinoma, gastric cancer, head and neck cancer, pancreatic carcinoma, brain cancer, colorectal carcinoma and melanoma.”

“Pursuant to the terms of this license, we are required to pay the NIH a cash payment in the aggregate amount of \$150,000, two-thirds of which was due and paid within sixty days of the date of the agreement and one-third of which will be payable upon the earlier to occur of (1) 18 months from the date of execution of the license and (2) the termination of the license. We also

⁴ https://www.sec.gov/Archives/edgar/data/1510580/000156459015001985/kite-10k_20141231.htm Pages 19-20

agreed to reimburse the NIH for past patent expenses in the aggregate amount of approximately \$30,000.”

“The terms of this license also require us to pay the NIH minimum annual royalties in the amount of \$20,000. The first minimum annual royalty payment is payable on the date that is 60 days following the expiration of the CRADA, and thereafter shall be payable on each January 1.”

“We are also required to make performance-based payments upon successful completion of clinical and regulatory benchmarks relating to the licensed products. The aggregate potential benchmark payments are \$4.0 million, of which aggregate payments of \$3.0 million are due only after marketing approval in the United States or in Europe, Japan, China or India. The first benchmark payment of \$50,000 will be due upon the commencement of our first sponsored human clinical study.”

“In addition, we are required to pay the NIH one-time benchmark payments following aggregate net sales of up to \$1.0 billion on licensed products. The aggregate potential amount of these benchmark payments is \$7.0 million. We must also pay the NIH royalties on net sales of products covered by the license at rates in the mid single digits. To the extent we enter into a sublicensing agreement relating to a licensed product, we are required to pay the NIH a percentage of all consideration received from a sublicensee, which percentage will decrease based on the stage of development of the licensed product at the time of the sublicense. Any such sublicense payments shall be made in lieu of, and not in addition to, benchmark payments, and are subject to certain caps.”

“The license will expire upon expiration of the last patent contained in the licensed patent rights, unless terminated earlier. None of the applications included in the NIH licensed patent rights have issued yet. Any patents issuing from these applications will have a base expiration date no earlier than 2031. The NIH may terminate or modify the NIH license in the event of a material breach, including if we do not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. We may terminate the license, or any portion thereof, at our sole discretion at any time upon 60 days written notice to the NIH. In addition, the NIH has the right to require us to sublicense the rights to the product candidates covered by this license upon certain conditions, including if we are not reasonably satisfying required health and safety needs or if we are not satisfying requirements for public use as specified by federal regulations.”

December 2014 National Institutes of Health ("NIH") License Agreement⁵

“Pursuant to a patent license agreement with the NIH, dated December 31, 2014, the Company holds an exclusive, worldwide license to certain intellectual property related to TCR-based product candidates that target HPV antigens E6 and E7 of the HPV subtype 16.”

⁵ <https://www.sec.gov/Archives/edgar/data/1510580/000151058017000003/kite20161231-10k.htm> Pages 89-90

“Pursuant to the terms of this license, the Company paid the NIH a cash payment in the aggregate amount of \$350,000 in February 2015. The Company is required to make performance-based payments upon successful completion of clinical and regulatory benchmarks relating to the licensed products. The aggregate potential benchmark payments for each licensed product are \$6.0 million, of which aggregate payments of \$5.0 million are due only after marketing approval in the United States or in Europe, Japan, China or India. The first benchmark payment of \$50,000 will be due upon the commencement of the Company’s first sponsored Phase 1 clinical trial. In addition, the Company is required to pay the NIH one-time benchmark payments following aggregate net sales of up to \$1.0 billion of licensed products. The aggregate potential amount of these benchmark payments is \$7.0 million. The Company must also pay the NIH royalties on net sales of products covered by this license at rates in the mid-single digits. To the extent the Company enters into a sublicensing agreement relating to a licensed product, the Company is required to pay the NIH a percentage of all consideration received from a sublicensee, which percentage will decrease based on the stage of development of the licensed product at the time of the sublicense. Any such sublicense payment is subject to a certain cap.”

“The license will expire upon expiration of the last patent contained in the licensed patent rights, unless terminated earlier. None of the applications included in the NIH licensed patent rights have issued yet. Any patents issuing from these applications will have a base expiration date no earlier than 2034. The NIH may terminate or modify the license in the event of a material breach, including if the Company does not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. The Company may terminate the license, or any portion thereof, at its sole discretion at any time upon 60 days written notice to the NIH. In addition, the NIH has the right to require the Company to sublicense the rights to the product candidates covered by the license upon certain conditions, including if the Company is not reasonably satisfying required health and safety needs or if the Company is not satisfying requirements for public use as specified by federal regulations.”

October 2015 NIH License Agreement⁶

“Pursuant to a patent license agreement with the NIH, dated October 1, 2015, the Company holds an exclusive, worldwide license to certain intellectual property related to TCR-based product candidates directed against MAGE A3 and A3/A6 antigens for the treatment of tumors expressing MAGE. Pursuant to the terms of this license, the Company paid the NIH a cash payment in the aggregate amount of \$1.2 million in November 2015.”

⁶ <https://www.sec.gov/Archives/edgar/data/1510580/000151058017000003/kite20161231-10k.htm> Page 90

“The Company is also required to make performance-based payments upon successful completion of clinical and regulatory benchmarks relating to the licensed products. The aggregate potential benchmark payments for each licensed product are \$8.4 million, of which aggregate payments of \$6.0 million are due only after marketing approval in the United States or in Europe, Japan, China or India. Also, a benchmark payment of \$150,000 will be due upon the commencement of the Company’s first sponsored Phase 1 clinical trial for each licensed product in each indication.”

“In addition, the Company is required to pay the NIH one-time benchmark payments following aggregate net sales of up to \$1.0 billion of licensed products. The aggregate potential amount of these benchmark payments is \$12.0 million. The Company must also pay the NIH royalties on net sales of products covered by this license at rates in the mid-single digits. To the extent the Company enters into a sublicensing agreement relating to a licensed product, the Company is required to pay the NIH a percentage of all consideration received from a sublicensee, which percentage will decrease based on the stage of development of the licensed product at the time of the sublicense. Any such sublicense payment is subject to a certain cap.”

“The license will expire upon expiration of the last patent contained in the licensed patent rights, unless terminated earlier. None of the applications included in the NIH licensed patent rights have issued yet. Any patents issuing from these applications will have a base expiration date no earlier than 2032. The NIH may terminate or modify the license in the event of a material breach, including if the Company does not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. The Company may terminate the license, or any portion thereof, at its sole discretion at any time upon 60 days written notice to the NIH. In addition, the NIH has the right to require the Company to sublicense the rights to the product candidates covered by the license upon certain conditions, including if the Company is not reasonably satisfying required health and safety needs or if the Company is not satisfying requirements for public use as specified by federal regulations.”



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

TO: NIH

FROM: Brandon Gaylord
FOIA Officer
FOI / Privacy Acts Division

DATE: August 28, 2020

SUBJECT: APPEAL
Requester/Appellant: **Kathryn Ardizzone/ Knowledge Ecology International**
Appeal Number: **2020-00288-A-PHS**
Orig. Case No: **45669**
Due Date: **September 11, 2020**

SUMMARY: *Challenges the response to NIH decision - Request # 45669*

 X DENIAL APPEAL (e.g., Expedited Processing, Fee Waiver, Withheld Information). Please review the attached appeal. If after re-evaluating the denial, you wish to have it upheld by the DSAPA/MEDIA, please provide me with copies of the material that was denied and a substantive argument for sustaining your position.

 B7(A) DENIAL. The FOIA requires the agency to provide to the requester any reasonably segregable portion of a record after deletion of the portions that are exempt. Please review the documents. Provide summary/examples of the information within the documents, including references and support for materials you believe would harm the investigation if released. Contact the official responsible for the investigation to confirm that said information would harm the investigation if released. Identify any other exemptions that protect the information from disclosure.

 ADEQUACY OF SEARCH APPEAL. Please review the attached appeal which challenges the search conducted by your agency. Please conduct a subsequent search for responsive records. If (additional) records are found, please provide a direct response to the appellant and provide this office with a copy of your response letter. If you do not locate (additional) records, please provide a detailed description of your search process. I've attached a copy our "DESCRIPTION OF FOIA SEARCH FOR DOCUMENTS" form which provides guidelines for what should be included in your support that you conducted a proper search. This information is needed because we may be called upon to defend your position in Court.

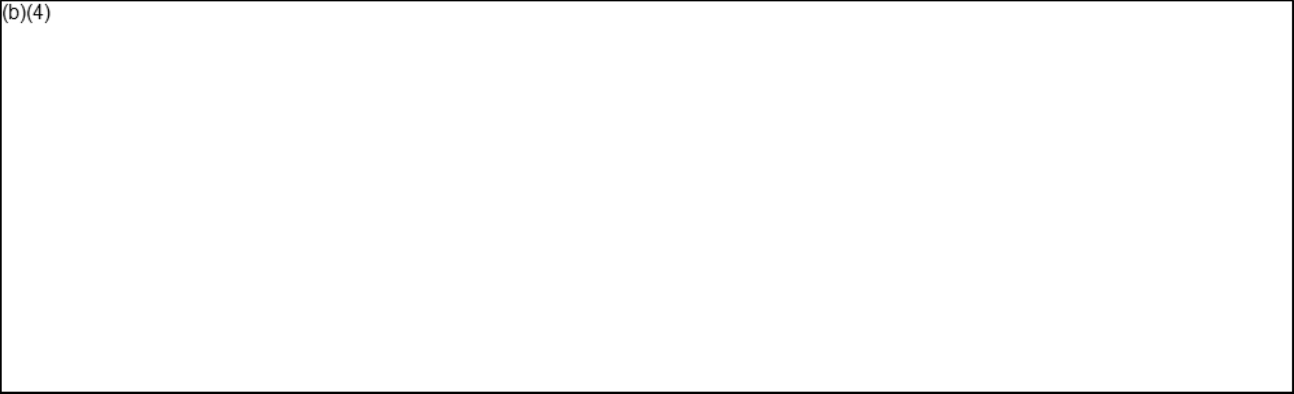
 Other: Constructive Denial

Attachments:

- X Appeal Letter
- Letter of Denial
- Description of Search form
- X Other

From: Milliard, Suzanne (NIH/NCI) [E]
Sent: Thu, 30 Apr 2020 17:52:59 +0000
To: Lampe, Karen (NIH/OD) [E]
Cc: NIH FOIA; Garcia-Malene, Gorka (NIH/OD) [E]
Subject: FW: NIH FOIA Request - 45669 KEI

(b)(4)



Importance: High

Hi Karen-

For Case 45669, attached are all RDFs between NCI and Kite Pharma. I was told you send these to you directly since the case is with KEI.

I explained to Gorka that NIH OTT or OFM or whoever is determined to be the responsible party should review these. In the past, OTT provided and redacted these for release, but since there is some confusion right now as to who should provide the records, we were happy to help and pull these from TechTracs.

Please let me know what else you need.

Suzy

From: Richard Rodriguez <richard.rodriguez@nih.gov>
Date: Thursday, April 30, 2020 at 10:25 AM
To: "Milliard, Suzanne (NIH/NCI) [E]" <milliards@mail.nih.gov>
Subject: RE: NIH FOIA Request - 45669 KEI

Hi Suzy,

Here are the forms that are responsive to this request.

Thanks,

Richard

From: Milliard, Suzanne (NIH/NCI) [E] <milliards@mail.nih.gov>
Sent: Tuesday, April 28, 2020 2:34 PM
To: Chamberlain, Bonnie (NIH/NCI) [E] <bonnie.chamberlain@nih.gov>; Rodriguez, Richard (NIH/NCI) [E] <richard.rodriguez@nih.gov>
Subject: FW: NIH FOIA Request - 45669 KEI
Importance: High

Hi Bonnie/Richard-

Well, it seems that we are responsible for gathering the records in response to Case 45669 (third attachment). I have been pushing back on principal because we are not the official record keeper, but now looks like we will be processing these. Just so you know, once this goes through, we will have to process these from now on...once something starts, it never ends. Not sure how much additional work this will be for my office as well as yours. Obviously, this is above my pay grade and I was the lone standout. Can you please provide the records as soon as possible since this case is extremely old.

Also, I have no history with these records, so please clarify what we should be redacting prior to release.

Suzy

From: "Bordine, Roger (NIH/OD) [E]" <roger.bordine@nih.gov>
Date: Tuesday, April 28, 2020 at 2:03 PM
To: "Milliard, Suzanne (NIH/NCI) [E]" <milliards@mail.nih.gov>
Cc: "NCI FOIA (NIH/NCI)" <ncifoia@mail.nih.gov>, NIH FOIA <nihfoia@od.nih.gov>
Subject: NIH FOIA Request - 45669 KEI

Good morning Suzy,

With regards to 45669, I know we've been going back and forth on this request for some time, and we recently checked with OTT and OFM officials (Karen Rogers), and based on the following, they posit that this should be processed at NCI, and Richard Rodriguez at NCI seems to agree:

"Regarding 45669 – NCI should respond to this request since any Royalty Distribution Forms (RDFs) originate from NCI Technology Transfer Office and they can be retrieved from the NIH TechTracS System of record. I've included a sample of how OTT has redacted RDFs for past FOIA requests that were processed prior to the Technology Transfer Reorganization. Richard Rodriguez has been copied and agrees that this request should be sent to NCI for a response. I wanted to share with all, since this is a frequent request through FOIA."

Based on the above, we plan to change the action office back to NCI in FXpress. Do you agree that this is the right way to proceed?

Thank you Suzy.

Roger Bordine
Program Support

Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov



From: Lampe, Karen (NIH/OD) [E]
Sent: Fri, 6 Mar 2020 18:40:37 +0000
To: Bordine, Roger (NIH/OD) [E]; Garcia-Malene, Gorka (NIH/OD) [E]
Subject: FW: OTT file requests

From: Lampe, Karen (NIH/OD) [E]
Sent: Thursday, January 23, 2020 9:53 AM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: RE: OTT file requests

Ok, thank you Roger!

From: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Sent: Thursday, January 23, 2020 9:52 AM
To: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: RE: OTT file requests

Gorka, myself, NCI and OTT have been communicating regarding 45699. The others were in Gina's (our contact at OTT) hands, but apparently, according to her supervisor at OTT, she's been out of office for some time now and that is why she's been unresponsive to my emails. (she forgot to put her Out-of-Office up before she suddenly left)

I can forward the emails I sent to her about the other two requests to her supervisor, but it will likely be like starting from scratch over there.

Sorry. We just found out this week that she's been gone.

- Roger

From: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Sent: Thursday, January 23, 2020 10:47 AM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: OTT file requests

Good morning Roger,
Have we heard anything from OTT on those royalty payment document requests yet? The FOIA request numbers are 51843, 46817 and 45699.

Thanks,

Karen E. R. Lampe, Ph.D.
Government Information Specialist
NIH Freedom of Information Office (HNA83)
karen.lampe@nih.gov

From: NIH FOIA
Sent: Mon, 29 Jul 2019 18:31:59 +0000
To: Garcia-Malene, Gorka (NIH/OD) [E]
Subject: FW: Status Inquiry - FOIA Requests
Attachments: FW: FOIA Request from OIG Web Site
Importance: High

Gorka,

KEI is asking about their older open cases below. They also submitted a request on the 15th for all comms related to these cases.

Please advise on how to proceed/respond.

Thank you Gorka.

- Roger

From: kathryn ardizzone <kathrynardizzonekei@gmail.com>
Sent: Monday, July 29, 2019 2:03 PM
To: NIH FOIA <nihfoia@od.nih.gov>
Subject: Re: Status Inquiry - FOIA Requests

Hi Mr. Bordine:

Thank you for that information, that is very helpful. Can you please perform the same inquiry for FR 45413, 45669, and 46817?

Sincerely,

Kathryn Ardizzone

On Mon, Jul 29, 2019 at 1:54 PM NIH FOIA <nihfoia@od.nih.gov> wrote:
Good Afternoon,

The NIH FOIA Office responded to the request, 47590 (Goldman/KEI) on April 19, 2018 via email to Andrew S. Goldman to andrew.goldman@keionline.org, with the final letter attached. The request was closed that same day, April 19, 2018. We have attached a copy of that email to Mr. Goldman, as well as a copy of the final letter sent to him.

Thank you.

Roger Bordine
Program Support
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35

31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov



From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Monday, July 29, 2019 1:03 PM
To: NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>
Subject: Status Inquiry - FOIA Requests

Dear Sir or Madam:

I am counsel with Knowledge Ecology International (KEI), and I am writing to inquire about the status of four outstanding FOIA requests that were submitted by KEI on February 21, 2018. The requests were all assigned the number 18-FOI-00196-OSP; 47590, and they request records regarding the NIH's obligations to seek antitrust advice under 40 USC § 559 (and earlier codifications of the statute, pertaining to the time period of codification).

As soon as practicable, please inform me of the status of these requests. Thank you in advance for your consideration.

Sincerely,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Economy International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

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Kathryn Ardizzone, Esq.
Knowledge Economy International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670

From: OIG, FOIA
Sent: Mon, 15 Jul 2019 15:14:15 +0000
To: NIH FOIA
Subject: FW: FOIA Request from OIG Web Site
Attachments: KEI FOIA request regarding previous FOIA requests.pdf

The attached FOIA request was sent to us by mistake.

Thanks,
OIG FOIA
202.619.2541

From: Web_Intake
Sent: Friday, July 12, 2019 2:39 PM
To: Web_Intake <Web.Intake@oig.hhs.gov>
Subject: FOIA Request from OIG Web Site

The Following Information was sent	
Title:	Miss
First Name:	Claire
Last Name:	Cassedy
Organization:	Knowledge Ecology International
Address 1:	1621 Connecticut Ave NW
Address 2:	Suite 500
City:	Washington
State:	DC
Zip Code:	20009
Daytime Phone:	202-332-2670
Email Address:	claire.cassedy@keionline.org
Document Discriptions:	Under the Freedom of Information Act (FOIA), Knowledge Ecology International (KEI) requests all records (including all emails and correspondence) related to the following Freedom of Information Act requests: 1. Request number 45413. Submitted August 11, 2016 by Andrew Goldman (Andrew.Goldman@keionline.org) and James Love (James.Love@keionline.org) seeking: "(1) any and all records or documents related to individual royalty payments for licensed technologies received by every current or former federal employee for whom the National Institutes of Health (NIH) administers royalty payments for, including employees of the NIH, Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA) between August 8, 2011 and August 8, 2016; and (2) any and all communications and correspondence to or from employees of the NIH, CDC, and FDA that mention the payment of such royalties to current or former

	individual employees of the NIH, CDC, and FDA between August 8, 2011 and August 8, 2016." 2. Request number 46817. Submitted August 28, 2017 by James Love (James.Love@keionline.org) via email inquiry to Karen Rogers, OTT (RogersK@mail.nih.gov) and forwarded to the FOIA office to be processed as FOIA request, seeking a copy of records involving who received royalties from the NIH in 2016. 3. Request number 45669. Submitted October 13, 2016 by Zack Struver (Zack.Struver@keionline.org) seeking: "...copies of the Royalty Distribution Forms for the following: A. All exclusive patent license agreements and Cooperative Research and Development Agreements (CRADAs between the National Cancer Institute and Kite Pharma, including the following: 1. CRADA No. 02716 (Signed by Kite on August 13, 2012); 2. License Application No. A-294-2011 (dated April 11, 2013); 3. License Application No. A-265-2013 (dated May 22, 2014); 4. License Application No. A-563-2014 (dated December 18, 2014); 5. License Application No. A-276-2014 (dated September 28, 2015); 6. CRADA No. 03019 (dated January 2, 2016) 7. CRADA (dated June 2016) 8. License Agreement (dated July 2016); and 9. License Agreement (dated September 2016); and B. And other agreements between Kite Pharma and NIH." The period of this request is from August 11, 2016 to the present.
Document Start Date:	08/11/2016
Document End Date:	07/12/2019
The Amount To Reimburse:	\$26.00 - \$100.00
How To Receive Documents:	Email (if documents are more than 5MB. they will be provided on a CD.)
Uploaded File :	KEI FOIA request regarding previous FOIA requests.pdf

From: Lampe, Karen (NIH/OD) [E]
Sent: Thu, 2 Jan 2020 14:33:01 +0000
To: Garcia-Malene, Gorka (NIH/OD) [E]
Subject: KEI royalty cases
Attachments: 51482 KEI FOIA request regarding previous FOIA requests.pdf, 45413 - Copy of Request.pdf, 45413 Goldman - Final Response.docx, Copy of Request 45669 with NIH FOIA notes written.pdf, 45669 Struver - Final Response.docx, 46817 Love - Final Denial Draft.msg, Copy of request - 46817.pdf, 51483 Cassedy.pdf, 51843 Cassedy - Final Response.pdf

Good morning Gorka, and Happy New Year! In looking again through the KEI royalty cases, it seems as though we closed one (51843) out this past fall, using b3 and b4. I've attached a copy of that request and the final letter sent, as well as drafts for the other cases (45413, 45669, and 46817 written by Roger last September). Because we've already denied one in full, I think we should deny the remainder in full, using the same letter as a template. This will leave open only a single case, 51842, which requests all records (including emails and correspondence) related to requests 45413, 46817 and 45669. It seems to me that we probably need to do a search of FOIA personnel emails for these records – what do you think?

Please let me know if you have any questions or need to discuss the approach.

Karen

Karen E. R. Lampe, Ph.D.
Government Information Specialist
NIH Freedom of Information Office (HNA83)
karen.lampe@nih.gov

Bordine, Roger (NIH/OD) [E]

From: Andrew S. Goldman <andrew.goldman@keionline.org>
Sent: Thursday, August 11, 2016 3:35 PM
To: NIH FOIA
Cc: Zack Struver
Subject: FOIA Request re: payment of royalties to current and former employees
Attachments: FOIA-NIH-payment-of-royalties-to-current-and-former-employees.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Ms. Cornell:

Attached, please find a FOIA request regarding (1) any and all records or documents related to individual royalty payments for licensed technologies received by every current or former federal employee for whom the National Institutes of Health (NIH) administers royalty payments for, including employees of the NIH, Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA) between August 8, 2011 and August 8, 2016; and (2) any and all communications and correspondence to or from employees of the NIH, CDC, and FDA that mention the payment of such royalties to current or former individual employees of the NIH, CDC, and FDA between August 8, 2011 and August 8, 2016.

Please let me know if you have any questions or concerns.

Sincerely,

Andrew S. Goldman
Counsel, Policy and Legal Affairs
Knowledge Ecology International
andrew.goldman@keionline.org // www.twitter.com/ASG_KEI
tel.: +1.202.332.2670
www.keionline.org



2016/493

From: Bordine, Roger (NIH/OD) [E]
Sent: Fri, 27 Sep 2019 20:17:01 +0000
To: Garcia-Malene, Gorka (NIH/OD) [E]
Subject: 46817 Love - Final Denial Draft
Attachments: 46817 Love - Final Response.docx

Hi Gorka,

Attached is the draft of the final denial letter to Love/KEI for 46817. Please review and sign.

Thanks.

Roger Bordine
Program Support
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via email: james.love@keionline.org

September 27, 2019

James Love
Director
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009

Re: FOI Case No. 46817

Dear Mr. Love:

This is the final answer to your August 28, 2016, Freedom of Information Act (FOIA) request addressed to the Office of Technology Transfer, (OTT) Freedom of Information (FOIA) Office, National Institutes of Health (NIH), which was forwarded to this office on that same day. You requested a copy of records involving who received royalties from the NIH in 2016.

The NIH Office of Technology Transfer (OTT) was consulted regarding records responsive to your request. I have determined to withhold those records pursuant to Exemptions 3 and 4 of the FOIA, 5 U.S.C. § 552 (b)(3) and (b)(4), and section 5.64 and 5.65 of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 3 protects from release records that are specifically exempt from disclosure by another federal statute. In this instance, the statute in question is the Federal Transfer and Technology Act, 15 U.S.C. Section 3710 a(c)(7)(A). Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged and confidential. In this case, the information withheld consists of non-public research.

You have the right to appeal this determination to deny you access to information in the Agency's possession. Should you wish to do so, your appeal must be sent within ninety (90) days of the date of this letter, following the procedures outlined in Subpart F of the HHS FOIA Regulations (<https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations>) to:

Assistant Secretary for Public Affairs
Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs, Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

Clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

If you are not satisfied with the processing and handling of this request, you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison

Stephanie Clipper
Public Affairs Specialist
Office of Communications and Public Liaison
Building 1 Room 331
1 Center Drive
Bethesda, MD 20892
301-496-1828 (phone)
nihfoia@mail.nih.gov (email)

OGIS

National Archives and Records Admin.
8601 Adelphi Rd – OGIS
College Park, MD 20740-6001
202-741-5770 (phone)
1-877-684-6448 (toll-free)
202-741-5769 (fax)
ogis@nara.gov (email)

In certain circumstances provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there is no charge associated with our response.

If you have any questions about this response, please call 301-496-5633.

Sincerely,

Gorka Garcia-Malene
Freedom of Information Officer, NIH

Love

DATE: 8/30/2017
DUE DATE: **9/14/2017**
TO: **Broyles, Stephanie**
OD/OFM
FROM: NIH FOIA Office, OD/OCPL
SUBJECT: FOIA Case No. 46817 - FOIA Log No. 2017/399

The attached FOIA request is forwarded to you for the following action:

FOR INPUT ONLY. Do not enter into the FOIA Tracking System. This case has been entered by the NIH FOIA Office which is coordinating the response. Before the noted due date, please provide the following information:

1. A cover memo from the FOI Coordinator. The cover memo should:
 1. Include a description of the search conducted. What files were searched, why were those files searched, would any other files have records, etc.;
 2. Explain any applicable fees to be charged;
 3. Describe the responsive records and how many pages are responsive to each item of the request;
 4. Address whether there is a no-records response to any item(s); and
 5. Provide a reference to the applicable records retention schedule if records have been destroyed.
 6. Include a releasability recommendation. If any records are proposed for withholding in full or in part, include a signed program statement addressing with specificity the harm that will result if the material proposed for redaction is released.
2. A completed copy of the records, indexed to the request, as the IC would like them released, i.e., with proposed redactions marked on the records:
 1. Hard Copy: If you send the records in hard copy, please either bracket or highlight any information proposed for redaction.
 2. Electronic: ~~If you send the records electronically, please mark the~~ information proposed for redaction (red boxes), but do not apply or permanently remove the information. Feel free to include notes on this version to help with the FOIA Office review.
 3. When sending records electronically, please save the records in separate folders, one with the unredacted/clean version of the records and one with the proposed redactions.

COMMENTS: See Email

NIH FOIA

From: Rogers, Karen (NIH/OD) [E]
Sent: Tuesday, August 29, 2017 12:50 PM
To: NIH FOIA
Cc: Thomas, Gina (NIH/OD) [E]
Subject: RE: Inquiry regarding TTC Inventor Royalties - Interim Letter 46817

Thanks Roger – OTT receives reports from OFM, but they (OFM) are the owners of the records and should be the ones responding. Karen

From: NIH FOIA
Sent: Tuesday, August 29, 2017 12:47 PM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Cc: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>; NIH FOIA <nihfoia@od.nih.gov>
Subject: RE: Inquiry regarding TTC Inventor Royalties - Interim Letter 46817

Hi Karen,

If you're 100% sure OTT does not have these records, and OFM does, then yes, do not respond to him at all. We'll change the wording in the interim letter to say that the request was referred to us by OTT FOIA.

Thanks Karen,

Roger Bordine
Program Assistant
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov



2017/399



From: Rogers, Karen (NIH/OD) [E]
Sent: Tuesday, August 29, 2017 12:45 PM
To: NIH FOIA <nihfoia@od.nih.gov>
Cc: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>
Subject: RE: Inquiry regarding TTC Inventor Royalties - Interim Letter 46817

Oh good. So just to confirm. I should not respond to Mr. Love at all? Karen

From: NIH FOIA

Sent: Tuesday, August 29, 2017 12:28 PM

To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>

Cc: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>

Subject: RE: Inquiry regarding TTC Inventor Royalties - Interim Letter 46817

Oh, my mistake Karen,

Ignore the previous emails then, we will handle this as OFM is responsive to this office.

Thanks and sorry for the confusion.

Roger Bordine

Program Assistant
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633

Fax: 301-402-4541

Roger.bordine@nih.gov



National Institutes of Health
Turning Discovery Into Health

From: Rogers, Karen (NIH/OD) [E]

Sent: Tuesday, August 29, 2017 11:59 AM

To: NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>

Cc: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>

Subject: RE: Inquiry regarding TTC Inventor Royalties - Interim Letter 46817

Thanks Roger – I was wondering why this isn't being forwarded to the Office of Financial Management for a response. They are the owners of record for the distribution of royalties. Regards, Karen

Karen L. Rogers
Acting Director
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, MD 20852
E-Mail: RogersK@nih.gov
Phone: 301-435-4359
Fax: 301-402-8678

SENSITIVE/CONFIDENTIAL INFORMATION

The attached information may be confidential. It is intended only for the addressee(s) identified above. If you are not the addressee(s), or an employee or agent of the addressee(s), please note that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this e-mail in error, please destroy the document and notify the sender of the error. Thank you.

From: NIH FOIA

Sent: Tuesday, August 29, 2017 11:08 AM

To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>

Cc: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>; NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>

Subject: RE: Inquiry regarding TTC Inventor Royalties - Interim Letter 46817

Hi again Karen,

Please see the attached draft Interim letter dated September 5th (I'd imagine that's when Gina returns) for her to sign and send out.

Thank you Karen,

Roger Bordine

Program Assistant

Freedom of Information Office

National Institutes of Health

Building 31, Room 5B35

31 Center Drive

Bethesda, MD 20892

Phone: 301-496-5633

Fax: 301-402-4541

Roger.bordine@nih.gov



From: Rogers, Karen (NIH/OD) [E]

Sent: Tuesday, August 29, 2017 10:18 AM

To: NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>

Cc: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>

Subject: RE: Inquiry regarding TTC Inventor Royalties

Thanks Roger. Appreciate the help. Karen

From: NIH FOIA
Sent: Tuesday, August 29, 2017 10:05 AM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Cc: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>; NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>
Subject: RE: Inquiry regarding TTC Inventor Royalties

Hi again Karen,

The NIH/OTT FOIA case number for this request is 46817.

I'm working on the interim letter for you now.

Thanks!

Roger Bordine
Program Assistant
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov



From: Rogers, Karen (NIH/OD) [E]
Sent: Tuesday, August 29, 2017 8:38 AM
To: NIH FOIA <[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov)>
Cc: Thomas, Gina (NIH/OD) [E] <gthomas@od.nih.gov>
Subject: FW: Inquiry regarding TTC Inventor Royalties

Good Morning NIH FOIA –

I received the request below from Mr. Love at KEI. Since Gina (OTT FOIA Coordinator) is out of the office this week, I'd like to request your assistance on the appropriate way to respond. I believe that OFM is the office of record for the royalty payout information. Regards, Karen

Karen L. Rogers
Acting Director
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325

Rockville, MD 20852
E-Mail: RogersK@nih.gov
Phone: 301-435-4359
Fax: 301-402-8678

SENSITIVE/CONFIDENTIAL INFORMATION

The attached information may be confidential. It is intended only for the addressee(s) identified above. If you are not the addressee(s), or an employee or agent of the addressee(s), please note that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this e-mail in error, please destroy the document and notify the sender of the error. Thank you.

From: jamespackardlove@gmail.com [mailto:jamespackardlove@gmail.com] **On Behalf Of** Jamie Love
Sent: Monday, August 28, 2017 2:32 PM
To: Rogers, Karen (NIH/OD) [E] <rogersk@od.nih.gov>
Subject: Inquiry regarding TTC Inventor Royalties

Karen Rogers (Team Lead)
Senior Royalties Administrator
Phone: 301-435-4359
Email: RogersK@mail.nih.gov(link sends e-mail)



Dear Karen Rogers,

KEI would like to know who received royalties from the NIH in 2016.

James Lvoe

--
James Love. Knowledge Ecology International
<http://www.keionline.org/donate.html>
KEI DC tel: +1.202.332.2670, US Mobile: +1.202.361.3040, Geneva Mobile: +41.76.413.6584,
twitter.com/jamie_love

2017/399

From: Broyles, Stephanie (NIH/OD) [E]
Sent: Mon, 27 Apr 2020 16:18:56 +0000
To: NIH FOIA; Bordine, Roger (NIH/OD) [E]
Subject: LOVE
Attachments: FOIA Request Love 46817.pdf

Good afternoon Roger:

Here is a copy of Love

Stephanie L. Broyles
Chief Administrative Officer
2115 East Jefferson Street
Room 3C308
Bethesda, MD 20892
(FOR DELIVERIES ONLY Rockville, MD 20852)
301-402-6260 (PHONE)

From: Lampe, Karen (NIH/OD) [E]
Sent: Thu, 21 May 2020 14:37:58 +0000
To: zack.struver@keionline.org
Cc: NIH FOIA; Lampe, Karen (NIH/OD) [E]
Subject: NIH FOIA Case No. 54669
Attachments: 45669 Final Response_Redacted.pdf, NIH FOIA 45669 Struver - Final Response Letter.pdf

Dear Mr. Struver,

Attached is our final response to your October 13, 2016 FOIA request number 54669. Please let me know if you have any questions.

Best Regards,

Karen E. R. Lampe, Ph.D.
Government Information Specialist
NIH Freedom of Information Office (HNA83)
karen.lampe@nih.gov

From: Bordine, Roger (NIH/OD) [E]
Sent: Thu, 18 Aug 2016 16:57:11 -0400
To: james.love@keionline.org
Cc: NIH FOIA
Subject: NIH FOIA Request - 45413 Love
Attachments: 45413 Love.pdf

Good Afternoon,

Please see the attached response to your NIH FOIA request.

Please let us know if you have any questions.

Thank you.

Roger Bordine

Program Assistant
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via email: james.love@keionline.org

August 18, 2016

James Love
Director
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009

Re: FOI Case No. 45413

Dear Mr. Love:

This acknowledges your August 8, 2016, Freedom of Information Act (FOIA) request addressed to the Freedom of Information (FOIA) Office, National Institutes of Health (NIH), which was received in our office on August 11, 2016. You requested a copy the following:

1. All records related to individual royalty payments for licensed technologies received by current and former federal employees for whom the NIH administers royalty payments, including employees of the NIH, Centers for Disease Control (CDC), and the Food and Drug Administration (FDA) between August 8, 2011 and August 8, 2016; and
2. Any and all communications and correspondence, in the form of emails, briefings, notes presentations or other formats, to or from employees of the NIH, CDC, and FDA that mention the payment of the royalties in Item 1 to current or former individual employees of the NIH, CDC, and FDA between August 8, 2011 and August 8, 2016.

We have queried the files of appropriate NIH offices for records responsive to your request. If any responsive documents are located, they will be reviewed for releasability, and all releasable information will be sent to you. We will do everything possible to comply with your request in a timely manner. Please feel free to contact me at [nihfoia@mail.nih.gov](mailto:.nihfoia@mail.nih.gov) or on (301) 496-5633 for additional information or to inquire about the status of your request.

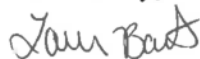
Provisions of the FOIA allow us to recover part of the cost of complying with your request. We shall charge you for records in accordance with the Department of Health and Human Services (HHS) FOIA Regulations as they apply to "other" requesters. As an "other" category requester you will be charged for duplication at 10-cents per page although the first 100 pages are free; 2 hours of search time are free and thereafter search time is charged at the hourly rate (\$23.00, \$46.00 and \$83.00) of the searcher; there is no charge for review time. Please be advised that the HHS FOIA Regulations allow us to charge for search time even if we do not locate any responsive records or if we determine that some or all of the responsive records are exempt under one of the FOIA's nine exemptions.

Because we are uncertain that any applicable fees will exceed our minimum charge (\$25.00), we are not addressing your request for a fee waiver at this time. However, if we determine there will be fees associated with processing your request, we will contact you at that time.

At any time during the processing of your request, you may seek assistance from the NIH FOIA Public Liaison:

NIH FOIA Public Liaison
Rosalee Dodson, Esq.
Building 31 Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892
301-496-5633 (phone)
301-402-4541 (fax)
[nihfoia@mail.nih.gov](mailto:.nihfoia@mail.nih.gov) (email)

Sincerely,



Lauren Bartok
Government Information Specialist, NIH

From: Bordine, Roger (NIH/OD) [E]
Sent: Wed, 30 Aug 2017 21:03:28 +0000
To: jamespackardlove@gmail.com
Cc: NIH FOIA
Subject: NIH FOIA Request - 46817 Love
Attachments: 46817 Love.pdf

Good Afternoon,

Please see the attached acknowledgment of your NIH FOIA request.

Thank you.

Roger Bordine
Program Assistant
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via email: james.love@keionline.org

August 30, 2017

James Love
Director
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009

Re: FOI Case No. 46817

Dear Mr. Love:

This acknowledges your August 28, 2016, Freedom of Information Act (FOIA) request addressed to the Office of Technology Transfer, (OTT) Freedom of Information (FOIA) Office, National Institutes of Health (NIH), which was forwarded to this office on that same day. You requested a copy of records involving who received royalties from the NIH in 2016.

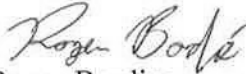
We have queried the files of appropriate NIH offices for records responsive to your request. If any responsive documents are located, they will be reviewed for releasability, and all releasable information will be sent to you. We will do everything possible to comply with your request in a timely manner. Please feel free to contact me at [nihfoia@mail.nih.gov](mailto:.nihfoia@mail.nih.gov) or on (301) 496-5633 for additional information or to inquire about the status of your request.

Provisions of the FOIA allow us to recover part of the cost of complying with your request. We shall charge you for records in accordance with the Department of Health and Human Services (HHS) FOIA Regulations as they apply to "other" requesters. As an "other" category requester you will be charged for duplication at 10-cents per page although the first 100 pages are free; 2 hours of search time are free and thereafter search time is charged at the hourly rate (\$23.00, \$46.00 and \$83.00) of the searcher; there is no charge for review time. Please be advised that the HHS FOIA Regulations allow us to charge for search time even if we do not locate any responsive records or if we determine that some or all of the responsive records are exempt under one of the FOIA's nine exemptions.

At any time during the processing of your request, you may seek assistance from the NIH FOIA Public Liaison:

NIH FOIA Public Liaison
NIH FOIA Office
Building 31 Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892
301-496-5633 (phone)
301-402-4541 (fax)
[nihfoia@mail.nih.gov](mailto:.nihfoia@mail.nih.gov) (email)

Sincerely,


Roger Bordine
NIH FOIA Office

From: Bordine, Roger (NIH/OD) [E]
Sent: Tue, 1 Nov 2016 16:25:42 -0400
To: zack.struver@keionline.org
Cc: NIH FOIA
Subject: NIH FOIA Request - Struver 45669
Attachments: 45669 Struver.pdf

Good Afternoon,

Please see the attached acknowledgement of your NIH FOIA request.

Please let us know if you have any questions.

Thank you.

Roger Bordine
Program Assistant
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via email: zack.struver@keionline.org

November 1, 2016

Zack Struver
Knowledge Ecology International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009

Re: FOI Case No. 45669

Dear Mr. Struver:

This acknowledges your October 13, 2016, Freedom of Information Act (FOIA) request addressed to the Freedom of Information (FOIA) Office, National Institutes of Health (NIH), which was received the same day. You requested copies of the Royalty Distribution Forms for the following:

- A. All exclusive patent license agreements and Cooperative Research and Development Agreements (CRADAs) between the National Cancer Institute (NCI) and Kite Pharma, including the following:
 - 1. CRADA No. 02716 (Signed by Kite on August 13, 2012);
 - 2. License Application No. A-294-2011 (dated April 11, 2013);
 - 3. License Application No. A-265-2013 (dated May 22, 2014);
 - 4. License Application No. A-563-2014 (dated December 18, 2014);
 - 5. License Application No. A-276-2014 (dated September 28, 2015);
 - 6. CRADA No. 03019 (dated January 3, 2016);
 - 7. CRADA (dated June 2016);
 - 8. License Agreement (dated July 2016); and
 - 9. License Agreement (dated September 2016); and
- B. Any other agreements between Kite Pharma and NIH.

We have queried the files of appropriate NIH offices for records responsive to your request. If any responsive documents are located, they will be reviewed for releasability, and all releasable information will be sent to you. We will do everything possible to comply with your request in a timely manner. Please feel free to contact me at nihfioia@mail.nih.gov or on (301) 496-5633 for additional information or to inquire about the status of your request.

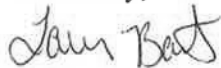
Provisions of the FOIA allow us to recover part of the cost of complying with your request. We shall charge you for records in accordance with the Department of Health and Human Services (HHS) FOIA Regulations as they apply to “other” requesters. As an “other” category requester you will be charged for duplication at 10-cents per page although the first 100 pages are free; 2 hours of search time are free and thereafter search time is charged at the hourly rate (\$23.00, \$46.00 and \$83.00) of the searcher; there is no charge for review time. Please be advised that the HHS FOIA Regulations allow us to charge for search time even if we do not locate any responsive records or if we determine that some or all of the responsive records are exempt under one of the FOIA’s nine exemptions.

Because we are uncertain that any applicable fees will exceed our minimum charge (\$25.00), we are not addressing your request for a fee waiver at this time. However, if we determine there will be fees associated with processing your request, we will contact you at that time.

At any time during the processing of your request, you may seek assistance from the NIH FOIA Public Liaison:

NIH FOIA Public Liaison
Marin Allen, Ph.D.
Admin.
Deputy Associate Director
Office of Communications and Public Liaison
Building 1 Room 344
1 Center Drive
Bethesda, MD 20892
301-496-4461 (phone)
301-496-0017 (fax)
[nihfoia@mail.nih.gov](mailto:.nihfoia@mail.nih.gov) (email)

Sincerely,



Lauren Bartok
Government Information Specialist, NIH

From: Bordine, Roger (NIH/OD) [E]
Sent: Fri, 12 May 2023 20:23:56 +0000
To: kathryn.ardizzone@keionline.org
Cc: NIH FOIA
Subject: NIH FOIA Requests - 53637 and 46817 Ardizzone - Final Response
Attachments: 53637 and 46817 Ardizzone - Final Response.pdf

Good afternoon,

Please see the attached final letter in response to your NIH FOIA requests.

Thank you.

Roger Bordine
Program Support
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541
Roger.bordine@nih.gov





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Email: kathryn.ardizzone@keionline.org

May 12, 2023

Ms. Kathryn Ardizzone
Knowledge Ecology International
1621 Connecticut Ave NW
Washington, DC, DC 20009

NIH FOIA Request Nos.: 46817 and 53637

Dear Ms. Ardizzone:

This is the final response to your August 28, 2017, Freedom of Information Act (FOIA) requests addressed to the FOIA Office at the National Institutes of Health (NIH) and received on the same day. You requested a copy of all records, of any kind, that mention royalty payments to Francis S. Collins, Ph.D., Director of the National Institutes of Health (NIH), from 2009 to present, as well as records that indicate who received royalties from the NIH in 2016.

Please be advised that the NIH FOIA Office is closing these two cases administratively because the responsive records have already been provided to you pursuant to NIH FOIA cases 51843 and 45413.

If you are not satisfied with the processing and handling of this request, you may contact the OD FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison

Denean Standing-Ojo
Public Affairs Specialist
Office of Communications and Public Liaison
Building 31, Room 5B52S
31 Center Drive
Bethesda, MD 20814
301-496-5077 (phone)
301-496-0818 (fax)
[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov) (email)

OGIS

National Archives and Records Admin
8601 Adelphi Rd - OGIS
College Park, MD 20740-6001
202-741-5770 (phone)
1-877-684-6448 (toll-free)
202-741-5769 (fax)
ogis@nara.gov (email)

In certain circumstances, provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there are no charges for search time.

If you have any questions about this response, please call the NIH FOIA office at 301-496-5633.

Sincerely,

Roger Bordine

Roger Bordine
Freedom of Information Office, NIH

From: Lampe, Karen (NIH/OD) [E]
Sent: Fri, 3 Jan 2020 18:14:27 +0000
To: Garcia-Malene, Gorka (NIH/OD) [E]
Subject: question for OTT
Attachments: 45413 - Copy of Request.pdf

Hi Gorka,
The question I have for OTT is as follows:

In reviewing the records provided for FOIA request 45413 (attached), we have a question about release of the name of the licensee. We are concerned that release of the name may inadvertently disclose a company's business plans to move into a research/development space, particularly in cases where the license may not have resulted from a CRADA. What is your position on release of the licensee name?

Please revise this as necessary 😊

Karen E. R. Lampe, Ph.D.
Government Information Specialist
NIH Freedom of Information Office (HNA83)
karen.lampe@nih.gov

From: Lampe, Karen (NIH/OD) [E]
Sent: Thu, 7 May 2020 15:16:19 +0000
To: Garcia-Malene, Gorka (NIH/OD) [E]
Subject: RE: 45669 Struver (KEI)

Ok.

From: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Sent: Thursday, May 7, 2020 10:05 AM
To: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: RE: 45669 Struver (KEI)

Please go back to Mark and ask him whether we have, in his estimation, a legal basis for withholding names. We would rather not provide any fodder for a new litigation when we might risk generating a bad decision against NIH.

From: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Sent: Thursday, May 7, 2020 11:03 AM
To: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Subject: RE: 45669 Struver (KEI)

What happened is this – Suzi sent them over to me as they'd been redacted by OTT In the past and I just forwarded them to Mark. He then agreed to the redactions. So we hadn't really thought about the fact that we were redacting the names

From: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Sent: Thursday, May 7, 2020 9:41 AM
To: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: RE: 45669 Struver (KEI)

Good morning, Karen –

Does this mean that we have determined not to release the names of royalty recipients?

From: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Sent: Thursday, May 7, 2020 8:32 AM
To: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Subject: 45669 Struver (KEI)

Hi Gorka,

Mark got back to me about the redacted records for request 45669 and they are ready to go out. The boxed file is attached – I've redacted under both b4 and b3 although it was only b4 when Mark looked at it. Are you ok with adding b3? I've also attached a draft final letter for your review and signature.

Let me know if you have any questions.

Karen E. R. Lampe, Ph.D.

Government Information Specialist

NIH Freedom of Information Office (HNA83)

karen.lampe@nih.gov

From: Bordine, Roger (NIH/OD) [E]
Sent: Thu, 17 Oct 2019 19:17:11 +0000
To: Garcia-Malene, Gorka (NIH/OD) [E]
Subject: RE: 46817

I pinged OFM about this and they will get back to us soon hopefully. Stephanie Broyles at OFM is our contact and she is often out of office so I've reached out the OFM helpdesk for suggestions on backups there for her.

Thanks.

- Roger

From: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Sent: Thursday, October 17, 2019 1:02 PM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: RE: 46817

Yes. I just need to see the records before I issue a denial

From: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Sent: Thursday, October 17, 2019 1:02 PM
To: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Subject: RE: 46817

Hi Gorka,

We sent a search out to OFM, but have not received a response, although we drafted the attached denial a while back.

Thanks.

- Roger

From: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Sent: Thursday, October 17, 2019 12:35 PM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: 46817

Hi Roger,

Did we ever receive records for this one?

From: Cornell, Susan (NIH/OD) [E]
Sent: Mon, 31 Oct 2016 07:08:12 -0400
To: Milliard, Suzanne (NIH/NCI) [E]; NIH FOIA
Subject: RE: ACTION: RE: Case 45669

We'll fix it – I'm here alone today until a detailee shows up but someone will get to it.

I don't think it was reassigned to NCI – I think you logged it in for us and we were supposed to change it to an OD case, which apparently never happened.



From: Milliard, Suzanne (NIH/NCI) [E]
Sent: Monday, October 31, 2016 6:33 AM
To: NIH FOIA <nihfoia@od.nih.gov>; Cornell, Susan (NIH/OD) [E] <CornellS@OD.NIH.GOV>
Subject: ACTION: RE: Case 45669
Importance: High

I think someone made a mistake – Looks like Case #45669 was reassigned to NCI...that is in error...Royalty distribution forms are held at the NIH OTT level. Susan and I have spoken about this and we said we would try to get the requester to agree to add this case into Case #45735, but that hasn't been agreed to by the requester yet.

Either way, the 45669 should be an NIH case and it was before, so not sure why it was changed to NCI.

Suzy

Suzy Milliard, CIPP/G
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Bethesda, MD 20892-2580

From: Garcia-Malene, Gorka (NIH/OD) [E]
Sent: Thu, 21 May 2020 14:17:08 +0000
To: Lampe, Karen (NIH/OD) [E]
Subject: RE: Case 45669 Struver
Attachments: NIH FOIA 45669 Struver - Final Response Letter.pdf

Thanks, Karen. This has to be one of the oldest 10 requests pending. I'm so glad this (multi-year) effort has come to a close.

Please don't forget the Buddy System.

Another KEI request done!

Gorka

From: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Sent: Thursday, May 21, 2020 8:14 AM
To: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Subject: FW: Case 45669 Struver

In case you didn't see this earlier this week.

From: Lampe, Karen (NIH/OD) [E]
Sent: Monday, May 18, 2020 11:39 AM
To: Garcia-Malene, Gorka (NIH/OD) [E] <gorka.garcia-malene@nih.gov>
Subject: Case 45669 Struver

Hi Gorka,
Attached is a draft final letter for your review and signature. I've also attached a copy of the redacted records and the request. Let me know if you have any questions.

Karen E. R. Lampe, Ph.D.
Government Information Specialist
NIH Freedom of Information Office (HNA83)
karen.lampe@nih.gov

From: Garcia-Malene, Gorka (NIH/OD) [E]
Sent: Mon, 29 Jul 2019 21:40:12 +0000
To: NIH FOIA
Subject: Re: Letter regarding FR 45413, FR 45669, and FR 46817

Wow. Let's discuss tomorrow morning. Please add this to the invitation, and make sure the latest request (today's, I think) has gone out for records and / or comment.

Thanks.
Gorka

On Jul 29, 2019, at 17:34, NIH FOIA <nihfoia@od.nih.gov> wrote:

Gorka,

KEI's latest email to us/HHS. Please take a look.

- Roger

From: kathryn ardizzone <kathryn.ardizzone@keionline.org>
Sent: Monday, July 29, 2019 5:26 PM
To: NIH FOIA <nihfoia@od.nih.gov>
Cc: Claire Cassedy <claire.cassedy@keionline.org>; James Love <james.love@keionline.org>
Subject: Letter regarding FR 45413, FR 45669, and FR 46817

Dear Sir or Madam:

Attached, please find a letter addressed to Catherine Teti, Deputy Agency Chief FOIA Officer for the NIH, from Knowledge Ecology International (KEI), discussing three FOIA requests filed between 2016 and 2017: FR 45413, FR 45669, and FR 46817. The letter also discusses a new request, submitted July 26, 2019.

Please do not hesitate to contact me with any questions about the letter.

Sincerely,

Kathryn Ardizzone, Esq.
Counsel
Knowledge Economy International
1621 Connecticut Avenue NW, Suite 500
Washington, DC 20009
kathryn.ardizzone@keionline.org
(202) 332-2670
<7.29.19 Letter from KEI to NIH re FR 45413 et seq.pdf>

From: Lampe, Karen (NIH/OD) [E]
Sent: Fri, 20 Dec 2019 14:08:35 +0000
To: Bordine, Roger (NIH/OD) [E]
Subject: RE: request letter for 45413

Thanks Roger!

From: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Sent: Thursday, December 19, 2019 4:32 PM
To: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Subject: RE: request letter for 45413

Hi Karen,

I found the request and have added it to the shared drive case folder. I've also attached it for you.

Thanks, and have a great weekend!

- Roger

From: Lampe, Karen (NIH/OD) [E] <karen.lampe@nih.gov>
Sent: Tuesday, December 17, 2019 3:04 PM
To: Bordine, Roger (NIH/OD) [E] <roger.bordine@nih.gov>
Subject: request letter for 45413

Hi Roger,

When you have a chance, do you think you could find and scan the request letter for 45413? I've looked in FX and in the shared drive case file and can't find a copy of the request.

Thanks,

Karen E. R. Lampe, Ph.D.
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